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Method for the identification and tracking of substances of concern in products and for the preparation of restriction measures on the use of substances in products

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Contents

Abstract

Within the context of the Ecodesign for Sustainable Products Regulation (ESPR) and after its entry into force in July 2024, the present report proposes a method for the definition and tracking of substances of concern in products (as defined in Article 2(27) of the ESPR) as well as for the assessment and preparation of potential restriction measures for substances impacting the product aspects listed in Article 5(1) of the ESPR. The method informs the setting of performance requirements and information requirements, when relevant for the product under study.

The intended audience for this report is primarily members of teams who will be undertaking Preparatory Studies for ESPR product groups, including from the European Commission, as well as stakeholders.

The suggested method builds upon the existing Methodology for Ecodesign of Energy-related Products (MEErP), which has been used successfully in the framework of the Ecodesign Directive. The method comprises the following main steps:

- a preliminary data gathering phase, resulting in an inventory of substances, to enable the chemical composition of the product Base Case(s) to be defined;
- the identification of substances of concern that should be subject to information requirements on tracking; and
- where appropriate, the development of considerations for performance requirements on substances occurring in the product or in its life cycle that negatively affect product aspects in Article 5(1), including the evaluation of alternatives to prevent regrettable substitution.

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Executive summary

The present report proposes a method for the definition and tracking of substances of concern in products (as defined in Article 2(27) of the ESPR) as well as for the assessment and preparation of restriction measures for substances impacting on the product aspects listed in Article 5(1) of the ESPR.

Policy context

In July 2024, Regulation (EU) 2024/1781 on the Ecodesign for Sustainable Products (ESPR) entered into force, with the aim of improving the environmental sustainability and the circularity of products placed on the market in the EU. The ESPR extends the scope of the Ecodesign Directive (Directive 2009/125/EC), now repealed, to also target non-energy-related and intermediate products. Moreover, it expands the focus on energy use to cover the full environmental sustainability profile of products throughout their life cycle, requiring the setting of information requirements on substances of concern and envisaging the possibility to set performance requirements on substances affecting different product aspects, which are listed in Article 5(1) of the ESPR. In order to define these substance-related product requirements in the ESPR, a method for the assessment and preparation of such restriction measures for substances is needed.

The ESPR is a framework regulation and product-specific ecodesign measures are implemented via delegated acts. To support the development of ecodesign measures, a research process is carried out, combining desk research with surveys, modelling and stakeholder consultation. As in the former 2009 Ecodesign Directive, these product-specific research findings are delivered in the form of a Preparatory Study, which informs the impact assessment and policy-making stages that result in a Commission proposal for a product-specific delegated act.

Intended audience for the report

The intended audience for this report is primarily teams who will be undertaking Preparatory Studies for ESPR product groups, whether from external consultancies or in-house at the European Commission, for example at the Joint Research Centre. This report also aims to connect the chemical “safety/risk assessment” and “Life Cycle Assessment/Ecodesign” communities, with regard to the enhanced remit in implementing the 2024 ESPR for product groups and horizontal design features. This method builds upon the existing Methodology for Ecodesign of Energy-related Products (MEErP) and incorporates three main sections, namely A, B, C, related to substances and in particular substances of concern.

The report should also facilitate the understanding and the nature of the work required for product-specific support on substances and substances of concern for societal and environmental NGOs, trade associations, manufacturers, importers and supply chain actors, academia, governments and think tanks, as well as other stakeholders including the European Commission. The report also aims to facilitate common ground and connections between the chemical “safety/risk assessment” and “Life Cycle Assessment/Ecodesign” practitioners and communities, with regard to the enhanced remit embedded in the 2024 ESPR, both for product groups and in addressing horizontal design features.

Key conclusions

Section A provides a method for **gathering preliminary data,** and for screening substances that remain in the product or are used or emitted along the life cycle of the product, based on their functionality. This assessment is to be performed to the extent that the available information and a proportionate use of resources allow, **prioritising information on substances remaining in the product**. Such a screening method allows the Preparatory Study team to develop the relevant chemical composition of a product Base Case; the method also guides practitioners through mapping substances in each life cycle stage, including end-of-life management/ recycling/ disposal, etc. This resulting Base Case chemical inventory is used to inform subsequent tasks, including the refinement of the Life Cycle Inventory (LCI), and the associated subsequent Life Cycle Assessment (LCA) of the product group under consideration.

Section B describes a method to **identify substances of concern, as defined in ESPR Article 2(27).** This starts from the inventory previously created which then becomes the basis for proposing the setting of potential information requirements i.e. for substances to be tracked in the products concerned. Given the relevance and novelty of these information requirements that are to be set as part of the ESPR, Section B provides **additional guidance and a discussion on thresholds, exemptions and deadlines for the entry into application** of the requirements being proposed. Also, this section guides the decision-making process on the review of the substances to track.

Section C proposes a method to develop performance requirements on substances in products or in their life cycle. Performance requirements could take the form of **specific bans, restrictions or other limitations in the conditions of use of substances that negatively affect the product aspects in Article 5(1).** In order to avoid regulatory overlap with other EU legislation (e.g., inter alia, REACH), performance requirements on substances will not be set under the ESPR for reasons relating primarily to chemical safety but, where appropriate, could be proposed for other sustainability reasons. In addition, as part of Section C, the report provides guidance for the evaluation of alternatives (preventing regrettable substitution).

A final **Section D** of the report provides an overview of the means to collect information on substances in products, such as the Digital Product Passport, and discusses appropriate verification mechanisms for the information and performance requirements in relation to substances.

In order to test and validate the proposed method, a **Case Study** has been developed. The Case Study (contained in Annex VI) has been conducted on a product group of high relevance to the ESPR, i.e. apparel textile products (clothing). The Case Study testing process helped to identify limitations and challenges, leading to iterative refinements of the method and improved product-specific guidance.

The method proposed in this report will be combined and integrated with the outputs of other ongoing work at the time of writing this report, with the aim of building a comprehensive methodology to support the setting of the ESPR requirements.

Main findings

The main findings of this report are presented in a guide describing the additional steps that should be performed in a Preparatory Study to address the assessment of substances in products and in their life cycle, building on the existing Methodology for Ecodesign of Energy-related Products (MEErP) tasks, as underlined below:

- Task 0: Quickscan. No additional steps proposed.
- Task 1: Scope. No additional steps proposed.
- Task 2: Market. No additional steps proposed.
- Task 3: Users. Additional steps proposed to identify substances specifically relevant to the use phase, such as substances released from the product.
- Task 4: Technologies. Additional steps proposed in order to gather information on the presence and use of substances in the life cycle of the product under analysis and their correlations with technologies (e.g. at the end-of-life stage).

— Task 5: Base Cases LCA and LCC. Additional steps proposed in order to include the information on substances in the definition of the Base Case(s)[1], which will be modelled in terms of their environmental impacts and cost aspects. In this task, substances of concern are also identified, as well as substances that may negatively affect one or more of the product aspects listed in Article 5(1) of the ESPR.

— Task 6: Design options. Additional steps are proposed, in order to define information requirements on tracking of substances of concern, and possible performance requirements for substances, if relevant. For possible performance requirements, any restriction on substances - in the form of a ban or limitation that would prevent the delivery of the required functionality - should be accompanied by an analysis of alternatives. This analysis is undertaken to ensure that alternative substances exist with a better safety and sustainability profile, and which result in acceptable trade-offs, compared to the substance(s) which are proposed to be restricted.

— Task 7: Scenarios. No additional steps proposed.

Related and future JRC work

The JRC has provided long-term support to policy DGs in terms of scientific evidence for informing the setting of ecodesign requirements as well as evidence-based research for chemical-related policies. The work presented in this report is part of the scientific support to formulate a methodology for the evaluation of products in the context of the ESPR. It has been performed in synergy with other tasks, collectively contributing to an ESPR methodology. The overall suite of ESPR-related methods will be made available in a combined and integrated format, with the aim of building a comprehensive methodology for practical use by Preparatory Study teams and interested parties in the process, to support the setting of ESPR requirements.

[1] According to the MEErP, the Base Case is “the average product on the EU market in terms of resource efficiency, emissions and functional performance. [...] The Base Case may or may not be a real product that one can buy on the market” (see also Section 3.1).

Extended executive summary

Aims and objectives. The present report proposes a method to define and track substances of concern in products (as a minimum) and throughout the life cycle of the products in question (i.e. in the form of information requirements) as well as to provide a decision process for the restriction of product-specific substances (i.e. in the form of performance requirements) in view of the implementation of the ESPR.

The intended audience for this report is primarily the teams who will be undertaking Preparatory Studies for ESPR product groups, as well as stakeholders, and the European Commission and it is intended to connect the "safety/risk assessment" and "Life Cycle Assessment/Ecodesign" communities, with regard to the enhanced remit in implementing the 2024 ESPR for product groups and horizontal design features.

Firstly, the report addresses the definition of **information requirements**, in order to enable the tracking of substances of concern (SoCs) throughout the life cycle of the products as defined in Article 2(27) of the ESPR. The presence of SoCs should also be assessed for recycled materials present in the product under analysis and in the recyclate resulting from end-of-life (EoL) treatments. Similarly, SoCs that are present along the life cycle of the product (as input and output flows, e.g. emissions, included EoL scenarios, etc.) should be considered, to the extent possible. Where the factual picture assembled is as complete as possible, this will enable the necessary flow of information between businesses, organisations, consumers and waste management operators (recyclers, preparation for reuse, etc.) via the digital product passport (DPP) or via other systems such as labels, tags, etc.

Secondly, this report addresses the possible setting of **product performance requirements** concerning the presence or use of substances, which include restrictions for reasons other than chemical safety. Although such restrictions are envisaged to be mainly product-focused (i.e. concerning substances in the product), relevant substances along the life cycle that do not remain in the product could potentially also be in the scope. Therefore, performance requirements will primarily focus on the 'product aspects' listed in Article 5(1), to the extent that a causal link can be found between these and the presence or use of a substance, with emphasis on the use of substances, and in particular the use of substances of concern (product parameter (f) in Annex I to the ESPR).

Structure of the report. The **method proposed in this report is structured in several sections**, namely Sections A, B, C and D:

- **Section A** constitutes the preliminary data-gathering steps for the method;
- **Section B** includes the method for developing information requirements for substances of concern;
- **Section C** constitutes the method for developing performance requirements on substances; and
- **Section D** explains the information to collect and how to verify product requirements on the presence of substances.

The method described in this report is intended to guide the developers of Preparatory Study product groups under assessment and subject to ESPR requirements.

A case study (provided in Annex VI) aims to test the method, illustrating possible challenges and proposing solutions, in the form of lessons learnt, to tackle such challenges.

A practical summary of the method is provided below for its integration with other ongoing tasks in the final ESPR methodology, based on the Methodology for Ecodesign of Energy-related Products (MEErP).

Task 0: Quickscan.

No additional steps proposed.

Task 1: Scope.

No additional steps proposed.

Task 2: Market.

No additional steps proposed.

Task 3: Users.

It is proposed to assess the substances in the use phase, both as substances used or emitted, including emissions resulting from wear during service life (e.g. from wear and tear due to the use of clothing), as well as substances added to the product by the user (to the extent possible) for instance in washing (substances contained in detergents) or do-it-yourself dying (substances from dyes used at home). In a simplified approach, the substances generated or emitted in the use phase would not be analysed. However, if stakeholder consultations give information regarding relevant substances that recyclers of consumer products scrutinise due to concerns about negative impacts on the recycling process or relevant for any product aspect (Article 5(1)), such information is documented and the substance(s) should de duly investigated and highlighted.

Task 4: Technologies.

The work in the Preparatory Study is strongly influenced by the findings in the initial stages of the project. A first quick scan of the product would help to define the scope of Task 1 of the MEErP and to determine the main areas of interest in terms of data collection and the analyses that will be the focus of Tasks 2 to 4. Moreover, information and data gaps should be anticipated to the extent possible. To complete this task, an **inventory of data on substances** (Section A of the present method), including substances that remain in the product as part of its chemical composition or substances used or emitted along the life cycle of the product, should be developed by the Preparatory Study team for the product group in question. Depending on the type of product, the complexity of its supply chain and the number of processes and substances involved in its manufacture, obtaining this information may be challenging. Proportionate efforts should be made, giving priority to substances that remain in the product but addressing, to the extent possible, substances relevant throughout the whole life cycle of the product.

Further details can be found in Chapter 3 ('Section A') of this report, which describes the preliminary steps for the method. Chapter 4 ('Section B') covers the method by which information requirements on substances of concern may be proposed. Subsequently, Chapter 5 ('Section C') gives details on the recommended method via which the setting of performance requirements may be proposed, concerning substances for reasons other than chemical safety, as prescribed by Article 6(3) of the ESPR.

Primarily, it is essential to obtain a deep understanding of the value chain of the product under assessment as well as of the product's material composition, as also specified in the MEErP. Additionally, it is important to have a good understanding of the chemicals in the materials in the product, and those relevant along its life cycle. Mapping this information in detail will help set information requirements and, as appropriate, performance requirements for substances. To the extent possible, this entails mapping not only intentionally added substances, but also substances which have not been intentionally added to the product, and substances used or emitted in the life cycle of the product. Acknowledging the challenges that such a series of tasks entails, this assessment should be carried out prioritising information on substances remaining in the product, whilst striving for a proportionate and efficient use of resources and of the available information.

In terms of timing, this initial information-gathering work can be carried out as part of Task 0 or throughout Tasks 1 to 4, as defined in the MEErP. Following the MEErP, this also means that the information gathered in Tasks 1 to 4 should enable clear identification of the Base Case(s) for the product group under analysis (Task 5), with necessary iterations between Tasks 1 to 5, as required. The Base Case(s) is then used as a reference for performing a hotspot analysis of the environmental impacts of the product. In turn, this constitutes the basis for developing and testing ecodesign requirements in Tasks 6 and 7.

Sections 3.2.1 'Product composition' and 3.2.2 'Life cycle stages' of the present report describe how to build the inventory of substances, and Section 3.3 outlines the building of the Base Case(s) (further described in Task 5 of the MEErP). The inventory of substances generated, together with their associated concentration ranges, where available, provide the necessary information required to propose possible ecodesign requirements related to substances. Consequently, Preparatory Study developers should strive to determine the **components, materials and substances** present in the product group (and subgroups) under analysis.

It is recommended to organise the information on the product composition and on its life cycle stages as proposed in **Table I** below (see also Table 1 in Section A), which constitutes the first step towards building the Base Case. To help the reader, **Table I** is shown below but it is worth noting that such table is the same as **Table 1** (included in the full method text, Section A). This approach is followed for some other relevant tables (Table I – B and Table II which correspond to Table 1 – B and Table 5 – B in the main text).

Table I. Inventory of the relevant components, materials and intentionally and non-intentionally added substances in the product and used in its life cycle (i.e. inputs and emissions).

		Substances in the product						Substances throughout the life cyle of the product							
Relevant Component (cp_i)	**Material (m_i)**	Intentionally added substance function class (f1)	Intentionally added substance (name + CAS number)	Concentration in the material or relevant component (as available)	Non-intentionally added substance type*	Non-intentionally added substance (name + CAS number)	Concentration in the material or relevant component (as available)	**Life cycle process (Pi)**	Intentionally used substance function class	Intentionally used substance (name + CAS number)	Amount/ Concentration (specify if related to the relevant component, material or product)	Non-intentionally used substance type*	Non-intentionally used substance (name + CAS number)	Amount/ Concentration (specify if related to the relevant component, material or product)	**Details/ Comments/ References**
cp_1	**m_1**	f1 e.g. dye	m1f1ch1 e.g. TiO2		e.g. by-product			P1 e.g. raw material extraction	e.g. lubricating agent						e.g. input or emission
			m1f1ch2						e.g. dye						
			m1f1ch3												
		f2 e.g. hardener	m1f2ch1												
			$m1ch_n$					P2							
			...					...							
	m_2	f1	m2f1ch1												
			m2f1ch2												
			...												
	m(r)		...												
	m_n														
...															
cp_2	...		...												
...															
cp_n															
...															
final product**	n.a.							P1 e.g. assembly							
	n.a.							P2 e.g. use							
	n.a.							P3 e.g. end-of-life							

Source: JRC's own elaboration.

* Specify if break-down products, impurities, side products or contaminants during the use or end-of-life stages.

** Materials and substances for final product are only in addition to those already considered in the other rows for components and materials.

Notation used: 'cp_i': component i, 'm_i': material i, 'f_i': function of the substance, '$m_if_ich_i$': intentionally added substances, 'm(r)': recycled material; Pi (e.g., P1, P2, P3 etc): life cycle process.

Table I provides the structured mapping of all intentionally and non-intentionally added substances[2] known to be in the product as well as of those used in its life cycle. More specific details are provided below:

- It serves to **map the intentionally and non-intentionally added substances** in the product under study as well as the related life cycle processes and substances involved, i.e. the input and output amounts for each life cycle stage and each manufacturing process are suggested to be included as well.
- It is divided into **two parts**. On the **left**, the intentionally and non-intentionally added substances that **remain in the product** should be collected. The function of the substances and the concentration in the material (or in the components) should be included, as well as other identification characteristics such as the hazard classification of the substances, the EC number, or other properties of interest. The presence and amount of any recycled material, if known, should be included.
- The **right side** of the table serves to collect information on the **substances** intentionally and non-intentionally used or emitted **during the life cycle of the product**, where the life cycle process should be included, indicating to which stage of the life of the product it belongs, i.e. extraction of raw materials, production, assembly, distribution, use or end-of-life, etc.
- The information collected will subsequently be used to build the **Base Case(s**), taking into account the scope of the product group under study, which will be defined in Task 5.

If simplified approach is needed, only half of the left part of **Table I**, corresponding to the intentionally added substances remaining in the products, should be completed. This is illustrated in **Table I – B** in next page.

2 For more details, see Section 3.2.2.

Table I – B. Inventory of the relevant components, materials and intentionally added substances in the product (i.e. inputs) (simplified approach).

		Substances in the product			
Component (cp_i)	**Material (m_i)**	Intentionally added substance function class (f1)	Intentionally added substance (name + CAS number)	Concentration in the material or relevant component (as available)	**Details/ Comments/ References**
cp_1	**m_1**	f1 e.g. dye	m1f1ch1 e.g. TiO2		e.g. input
			m1f1ch2		
			m1f1ch3		
		f2 e.g. hardener	m1f2ch1		
			$m1ch_n$		
			...		
	m_2	f1	m2f1ch1		
			m2f1ch2		
			...		
	m(r)		...		
	m_n				
cp_2	...		...		
...					
cp_n					
...					
final product**	n.a.				
	n.a.				
	n.a.				

Source: JRC's own elaboration.

** Materials and substances for final product are only in addition to those already considered in the other rows for components and materials.

Notation used: 'cp_i': component i, 'm_i': material i, 'f_i': function of the substance, '$m_i f_i ch_i$': intentionally added substances, 'm(r)': recycled material

Task 5: Base Case LCA and LCC.

Task 5 of the MEErP includes the definition of a Base Case, which will be analysed in terms of its environmental hotspots and cost aspects using LCA and Life Cycle Costing (LCC) modelling. This requires that the Preparatory Study team investigates and defines the life cycle of the product under analysis, where material and energy inputs through the various life cycle stages are modelled to obtain the environmental impact profile of the products in scope. This entails the identification of the **main life cycle stages** that constitute the value chain of the Base Case(s) (and its subgroups), from cradle to grave. As such, this includes the extraction of raw materials, any intermediate stage, the manufacturing of the components, materials and the final product, the placement of the final product on the market, its use by the customer and the end-of-life stages once the product is discarded by the user.

The Preparatory Study team should also identify, for each of the life cycle stages, the **processes and subprocesses** involved for the product group under study. The data collected in Table I represents the starting point for developing the LCA and LCC modelling as far as chemicals are concerned. Clearly, assessments carried out under the ESPR have to "look backwards" (to legacy chemicals) and "look forward" (to the recycling phase) to a far greater extent than is the case under the Ecodesign Directive, as applied to date to energy-related products.

For **substances**, the Preparatory Study team should consider a greater variety of substances for the Base Case than that normally comprised in a "average product on the market approach". This approach should take into account information from stakeholders, as well as evidence found in academic and "grey" literature. The approach proposed can be considered a **worst-case approach**. This approach would consider and quantify more substances than the average use of substances in products on the market (i.e. the Base Case(s)). Therefore, the approach can be more appropriately defined as a **pseudo-worst-case approach** given it acknowledges that in most cases it will not be possible (and indeed would be unnecessarily over-conservative) to build an inventory or define a Base Case which accounts for all possible substances relevant to the product group concerned.

To achieve the above, it is suggested that the Preparatory Study team analyses the substances used in the product under analysis **in two steps**, firstly defining an **inventory** of the main substances (and their concentration) used in the product and its life cycle, and secondly, starting from this compiled inventory, **building the Base Case(s)** relying on representative substances only.

The subsequent step of the method requires the identification of substances of concern that are present in the product, as defined in Article 2(27) (a), (b), (c) and (d) of the ESPR (**Section B of this report**) and which is proposed to be carried out as part of Task 5 of the MEErP. In greater detail, Section B is structured as follows:

- Section B1 addresses the identification of SoCs under Art. 2(27) (a), (b), and (c).
- Section B2 focuses on SoCs under Art. 2(27) (d), which recommends that this part of the method should be carried out in the MEErP Task 5.
- Section B3 (Defining information requirements for SoCs under Art. 2(27)) should be part of Task 6 of the MEErP, in order to propose information requirements on SoCs previously identified and defined under Art. 2(27) (a), (b), (c) and (d). The identification of such substances, and having an understanding of the relevant classification of the substances, serves two purposes:
    - It informs the content of the LCA model, regarding relevant substances to be considered, to the extent this may be possible.
    - It supports the identification of substances falling under the category of SoCs (d). Such substances must ultimately be listed in the delegated act. It also serves the purpose of providing a non-exhaustive list of possible SoCs (a), (b) and (c) in the product, which may be of use to operators in complying with their obligation to provide information on SoCs in their products.

The starting point for the Section B1 assessment is the inventory of substances in the product group under analysis (Table I), which results in the Base Case inventory of substances. The Preparatory Study should then use the Base Case inventory to determine which of the substances present meet the following criteria:

- **Substances of concern defined under Art. 2(27) (a)** → those that meet the criteria laid down in Article 57 of Regulation (EC) No 1907/2006 (REACH), as amended, and that are identified in accordance with Article 59(1) of that Regulation.
- **Substances of concern defined under Art. 2(27) (b)** → those classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 (Classification, Labelling and Packaging of Substances and Mixtures - "the CLP Regulation"), in one of the following hazard classes or hazard categories: *carcinogenicity categories 1 and 2, germ cell mutagenicity categories 1 and 2, reproductive toxicity categories 1 and 2, Endocrine disruption for human health categories 1 and 2, Endocrine disruption for the environment categories 1 and 2, Persistent, Mobile and Toxic or Very Persistent, Very Mobile properties, Persistent, Bioaccumulative and Toxic or Very Persistent, Very Bioaccumulative properties, respiratory sensitisation category 1, skin sensitisation category 1, chronic hazard to the aquatic environment categories 1 to 4, hazardous to the ozone layer, specific target organ toxicity – repeated exposure categories 1 and 2, specific target organ toxicity – single exposure categories 1 and 2.*

- **Substances of concern defined under Art. 2(27) (c)** → those regulated under Regulation (EU) 2019/1021 on persistent organic pollutants (POPs).

The method proposes the identification of substances of concern under **Article 2(27) (d)** that could be present in the final product, remain in the waste and/or hinder its reuse and/or recycling. Given that this step of the method is highly dependent on the information gathered from recycling companies, companies buying recycled materials and available literature, the identification of SoCs (d) in the product will also require the reconsideration of the substances previously identified in Table I. It may be that recycling companies flag the presence of substances which have not been previously identified by the Preparatory Study team via literature reviews, desk studies and initial interviews/questionnaires, etc, in which case this new information will make the already compiled inventory of substances (as in Table I) more complete. It is recommended that the Preparatory Study team distinguishes between intentionally added substances that were used to achieve a certain product function and non-intentionally added substances. In a simplified approach, the suggested distinction is removed, to focus solely on intentionally added substances remaining in the products under study (Table I – B).

In order to identify SoCs under Article 2(27) (d), it is proposed that the Preparatory Study team assesses both of the following:

- Existing **regulatory limitations** to the placing on the market or use of substances (in force or in preparation), as well as **customer-driven limitations** that are specified along the supply chain (which may be more rigorous, or of a different nature). This screening is also relevant for identifying substances in the product that could be identified as SoCs under criteria (a), (b) and (c) of Article 2(27).
- **Technical constraints**, interfering with the processes leading to reuse, preparing for reuse or recycling, or with the functionality, usefulness, value and aesthetics of the resulting recycled materials or products for reuse (as specified in Article 5(14)).

Table 4 (in the main text of this report) provides a non-exhaustive list of substances which, based on an assessment of the limited available literature, could qualify as substances that hinder recycling and/or reuse due to technical constraints associated with their effect on waste treatment processes or on the quality, performance and use of the resulting recyclate, or when prepared for reuse of products.

The Preparatory Study team is advised to assess and analyse available literature and carry out targeted stakeholder consultations in order to draft a list of candidate substances to be classified as SoCs under Art. 2(27) (d). This draft list should be shared with stakeholders in order to seek further feedback on whether the candidate substances indeed meet the criteria to be treated as SoCs under Art. 2(27) (d). Based on stakeholder feedback, and upon further investigation, the Preparatory Study team should then list those substances proposed as meeting Art. 2(27) (d) criteria. The Preparatory Study team could also consider organising, during the development of the Preparatory Study, specific working groups with a subset of stakeholders in order to discuss specific substances and, in particular, substances of concern.

Once the identification of substances of concern under Art. 2(27) (a), (b), (c) and (d) has been finalised and used to complement **Table I**, the definition of the Base Case(s) for (relevant) chemical composition should be possible. For this purpose, it is suggested to develop **Table 5** (in the main text of the report), which adapts **Table I** to reflect the Base Case(s). Table 5 includes columns which the Preparatory Study team should complete, regarding use and emission of intentionally and/or non-intentionally added substances in the product and along the Base Case life cycle, and whether they are SoCs (red columns). This analysis informs the LCA of the Base Case(s) and contributes to the identification of environmental hotspots, e.g. related to toxicity or energy use, for which chemicals may be relevant.

Where the simplified approach is followed, only intentionally added SoCs remaining in the products under study should be reflected in such a table (see **Table II** below).

Table II. Summary of intentionally added substances in the Base Case product (i.e. inputs) that are identified as SoCs under Art. 2(27) of the ESPR (simplified approach).

		Substances in the product				
Component (cp_i)	**Material (m_i)**	Intentionally added substance function class (f1)	Intentionally added substance (name + CAS number)	Concentration in the material or relevant component (as available)	Identified as SoC under Art. 2(27)	**Details/ Comments/ References**
cp_1	**m_1**	f1 e.g. dye	m1f1ch1 e.g. TiO_2			e.g. input
			m1f1ch2			
			m1f1ch3			
		f2 e.g. hardener	m1f2ch1			
			$m1ch_n$			
			...			
	m_2	f1	m2f1ch1			
			m2f1ch2			
			...			
	m(r)		...			
	m_n					
cp_2	...		...			
...						
cp_n						
...						
final product**	n.a.					
	n.a.					
	n.a.					

Source: JRC's own elaboration.

** Materials and substances for final product are only in addition to those already considered in the other rows for components and materials.

Notation used: 'cp_i': component i, 'm_i': material i, 'f_i': function of the substance, '$m_if_ich_i$': intentionally added substances, 'm(r)': recycled material

At the discretion of the study team, in a somewhat more elaborate adaptation of the simplified approach, SoCs highlighted by stakeholders or noted in literature as being relevant, because they are environmental hotspots, could still be included in the inventory even if related to emissions to air, water and soil along the life cycle stages. Similarly, substances that are not intentionally added but are present in the product, which are identified as adversely impacting the recycling and reuse of materials, could also be included in the inventory.

Task 6: Design options.

In addition to the work to be fulfilled under Task 6 of the MEErP, there are other recommended subtasks to be carried out, as part of the work defined in this methodology on substances. In particular, **Section B3** suggests the method by which the Preparatory Study team should define the **information requirements** on substances of concern, followed by **Section C**, which suggests how to propose **performance requirements** on substances.

<u>Information requirements – Section B3.</u>

The Preparatory Study team has the key task to identify and establish the minimum concentration thresholds that should trigger the information requirement for SoCs, for the product group under consideration (i.e. the concentration values below which substances of concern do not need to be tracked). This entails the following steps:

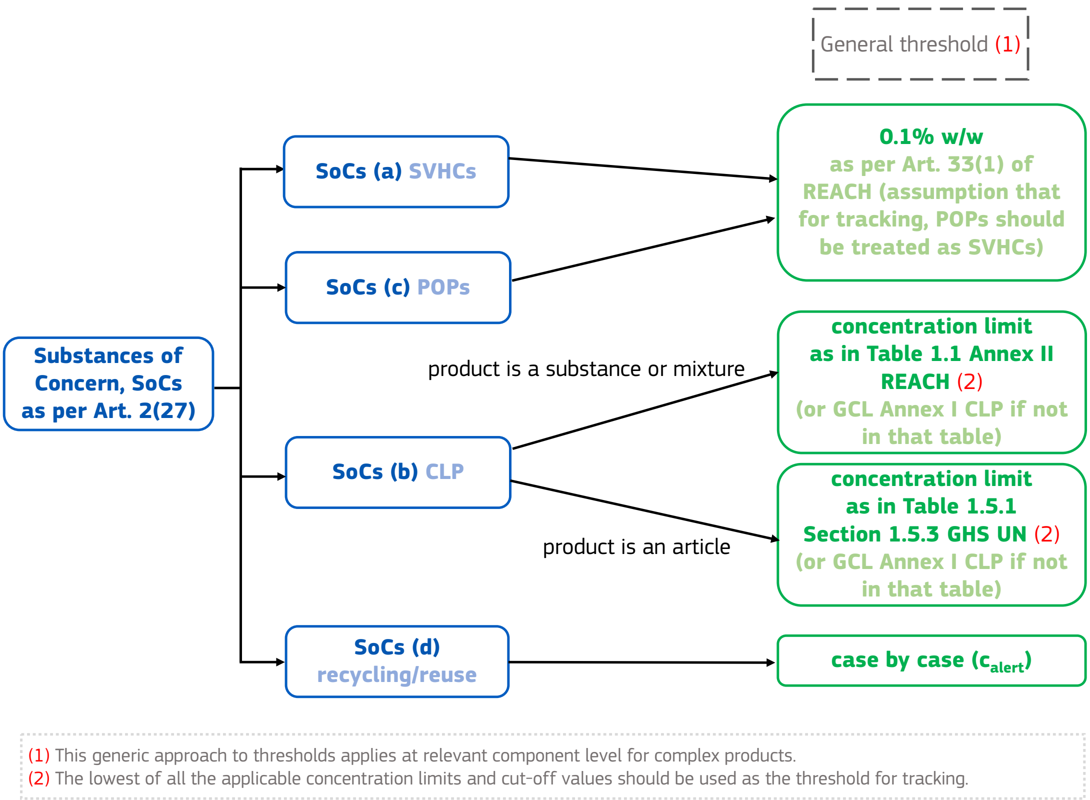
- suggesting general thresholds ensuring consistency with other related horizontal European Union legislation;
- considering the possibility of setting specific thresholds (potentially stricter than those set by regulatory requirements mentioned in the previous point);
- assessing other sources that could be used, where there is little or no data available.

Where a substance may be assigned to more than one of the ESPR SoC categories (e.g. a SoC which is both type (a) and (d)), the threshold triggering the information requirement should be conservatively defined, i.e. considering the lowest value among the criteria identified for the different SoCs.

In relation to **thresholds**, within this method it seems appropriate to suggest the alignment of the threshold for information requirements for safety-related SoCs (i.e. those under Art. 2(27) (a), (b) and (c)) with the relevant thresholds established in other EU legislation. Based on the substance and its regulatory framework, two approaches are possible: a generic approach (default) and a substance-specific approach to thresholds (to be used as appropriate and depending on available substance-specific information).

Two approaches are recommended, as summarised in **Figure I**: a **generic approach**, and a **substance-specific approach**, both of which are based on both EU and international chemicals-related legislation and guidelines/accepted practices.

Figure I. Approach to thresholds. Notation used: CLP: Classification Labelling and Packaging Regulation; GCL: generic concentration limits; GHS: globally harmonised system; POPs: persistent organic pollutants; REACH: Regulation for the Registration, Evaluation, Authorisation and Restriction of Chemicals; SoCs: substances of concern; SVHCs: substances of very high concern.



Source: JRC's own elaboration.

<u>Generic approach to thresholds, using EU "chemicals" legislation and terminology as the basis (primarily REACH and CLP)</u>

- For **SoCs under Art. 2(27) (a) and (c)** present in products that are **articles** (according to the definition contained in REACH, Art. 3.3), it is suggested to set a threshold of 0.1% w/w. This is in line with the information obligation for substances of very high concern in articles according to Article 33(1) of REACH. For SVHCs present in products that REACH defines as "**substances or mixtures"**, the same threshold of 0.1% w/w is proposed to be applied. Equally, all POPs are proposed to be treated as if they were listed as SVHCs in the Candidate List and therefore a threshold value of 0.1% w/w is also proposed.
- In the case of **SoCs under Art. 2(27) (b)**, a differentiated approach may be considered, depending on whether the product in scope is a **substance/mixture** or an **article** (as defined in REACH legislation, as above):

  (1) For **SoCs under Art. 2(27) (b) in products** within the scope of the ESPR **which are substances and mixtures**, it is suggested to set a generic threshold equal to the concentration limits in Table 1.1 of Annex II to REACH (referring to substances that should be listed in the safety data sheets of mixtures that are classified as hazardous, according to the CLP Regulation). There may be occasions where a relevant hazard class or category is not listed in Table 1.1 but does appear in Annex I to the CLP Regulation with a generic concentration limit (GCL), as applicable for the classification of mixtures. In such cases, the Preparatory Study team should use the *lowest generic concentration limit (GCL) value* for the substance in the class/category that leads to classification, to the extent that this information is available.

  (2) For **SoCs under Art. 2(27) (b) in products which are articles**, it is suggested to set a generic threshold equal to the cut-off values in Table 1.5.1 provided in Section 1.5.3 on "General guidance for compiling safety data sheets" of the Globally Harmonized System of Classification and Labelling of Chemicals (GHS). These values indicate the minimum information on hazardous constituents that should be available, internationally, in all Safety Data Sheets (SDS) that are produced in compliance with the GHS system. Where a relevant hazard class or category is not listed in the above-mentioned table, but does appear in Annex I to the CLP Regulation with a generic concentration limit (GCL), as applicable for the classification of mixtures, the following is recommended: the Preparatory Study team should use the lowest generic concentration limit value for the substance in the appropriate class/category that leads to classification of the mixture (where this information can be feasibly obtained).

  For **SoCs under Art. 2(27) (b),** the *lowest of all the applicable concentration limits and cut-off values* (corresponding to the hazard classes applicable to the substance) should be used as the threshold for tracking.

<u>Substance-specific approach to thresholds</u>

This involves two main cases:

- SoCs as defined in ESPR Art. 2(27) (d);
- SoCs covered by ESPR Art. 2(27), subject to other relevant legal restrictions related to products.

<u>(i) SoCs under Art. 2(27) (d)</u>

These SoCs represent a class of substances which the ESPR defines for the first time in EU legislation. Art. 2(27) (d) addresses substances that hinder the circularity of products (including recycling). For such substances, each ESPR product-specific delegated act will propose a list of substances to be tracked, which will be specific to the product(s) or product group(s) under consideration.

Given the specific nature of Art. 2(27) (d) SoCs, it is recommended to establish **thresholds based on the information collected** via stakeholder consultation among recycling/reuse companies, as well as literature sources, as part of the Preparatory Study work carried out. The data sought include the concentrations of SoCs identified under Art. 2(27) (d) that interfere with the recycling, or preparation for reuse processes, and also related to the quality of the recyclate, i.e. the **alert concentration** (c_{alert}) **for technical constraints** as defined in **Section B2**.

<u>SoCs under Art. 2(27) subject to other legal restrictions related to products</u>

These SoCs include specific restrictions under REACH, or those derived from the POPs Regulation, and apply to a substance in a given material or type of article.

Where there is a legal SoC restriction stemming from other legislation, a **case-by-case assessment** is proposed to assess the relevance of a product-specific limit, with respect to the overall destination market for the potentially affected recycled material. This assessment must determine whether the limit proposed in the other EU legislation is relevant with respect to the specific recyclate stream.

In general, where there are **substances of concern restricted in other (non-ESPR) product regulations**, this implies that, legally, no products should be placed on the EU market which contain concentrations above the appropriate restriction limit values of the relevant substance(s) applied by the other EU legislation, unless derogations exist for such restrictions.

This consideration opens up two possible approaches for the setting of specific thresholds under the ESPR (hereafter referred to as **c_{alert} for regulatory limitations**):

(i) An information threshold could be proposed, that is lower (i.e. stricter) than the restriction limit value set in the other applicable EU legislation.

(ii) An exemption from ESPR information requirements could be proposed for the restricted substance(s), where the restriction limit emanating from the other EU legislation is lower than or equal to the **generic threshold** (as proposed in the previous section, above).

Those substances falling under the above situations require case-by-case assessment within each individual Preparatory Study, and/or in the subsequent Impact Assessment supporting the Delegated Act, with regard to proposing the setting of requirements for the product. Regardless of whether the approach taken is generic or substance-specific, the thresholds proposed above should be considered as applying at the product or "relevant component" level.

For products that do not include components, and also for products that are mixtures, the minimum concentrations for complying with ecodesign information requirements should be the generic thresholds above, applied at the level of the product. The Preparatory Study team is advised to consider and propose a calculation approach, indicating the required level of granularity, taking into account provisions in the ESPR legal text, as well as the applicable jurisprudence at the time of performing the Preparatory Study, and applicable considerations of feasibility and proportionality.

Where the substance(s) and related threshold(s) identified for SoCs (d) is derived from a **customer-driven specification** (hereafter referred to as **c_{alert} for customer limitations**), as opposed to other EU legislative requirements, the threshold identified for triggering such a limitation should be investigated to demonstrate that it constitutes an actual barrier to circularity. This should be determined via evidence collected from stakeholders during consultations, upheld, where possible, by literature/feedback from technical inspections from Member States' ministries, inspectorates or agencies, etc.

Where the Preparatory Study team discovers the presence of **regulatory and customer chain limitations** for SoCs under Art. 2(27) (a), (b) and (c), this also categorises the substances as SoCs under Art. 2(27) (d) (respectively for regulatory and customer chain limitation). When this occurs, in the context of setting thresholds, it is important to clarify that the **strictest threshold should apply**.

In Task 6, information should also be collected regarding justifiable potential **exemptions** from the tracking obligations. Stakeholders should be consulted regarding this, via two of the public consultations that occur during the Preparatory Study. Information on the need for exemptions should be collected and subsequently assessed by the Preparatory Study team.

Aspects to consider when assessing whether exemptions for substances could be appropriate include: **technical feasibility**, the **relevance of tracking of substances of concern**, the existence of **analytical methods** for analysing substances, the protection of **confidential business information** (CBI), and other duly justified reasons. A simplified broader approach to exemptions, that takes into account the risk of disproportionate administrative burdens or challenges in verifiability, can be considered in duly justified cases. Different levels of ambition could potentially be proposed in terms of the granularity of families/groups of SoCs exempted from the information requirements and assessed at the Impact Assessment stage and tested as distinct policy options. The information on substances identified during the Preparatory Study (**SoCs under Art. 2(27)**) results in a (tentative, non-exhaustive) **Bill of Substances of Concern (Bill of SoCs).** This Bill of SoCs represents a list of substances proposed for information requirements, to thus enable their tracking along the value chain, if present in a product above the defined thresholds (subject to potential exemptions), determined as outlined above.

Table 5 (Section B2) contains the elements to be listed in the **Bill of SoCs**. **Table 6** (included in the report in the summary of Section B) should be used to extract the information concerning SoCs. To complement the name and function of the SoCs identified, their CLP classification should also be added (not included in Table 6, to reduce its size). However, the CLP information should be included in the Preparatory Study, at the relevant product/product group level at least for intentionally added substances remaining in the product (**Table II**).

The mapping of the different SoCs identified as relevant for the product group under consideration, together with their function, hazard classification and other elements, e.g. as collected via stakeholder consultations, constitute the basis for the following:

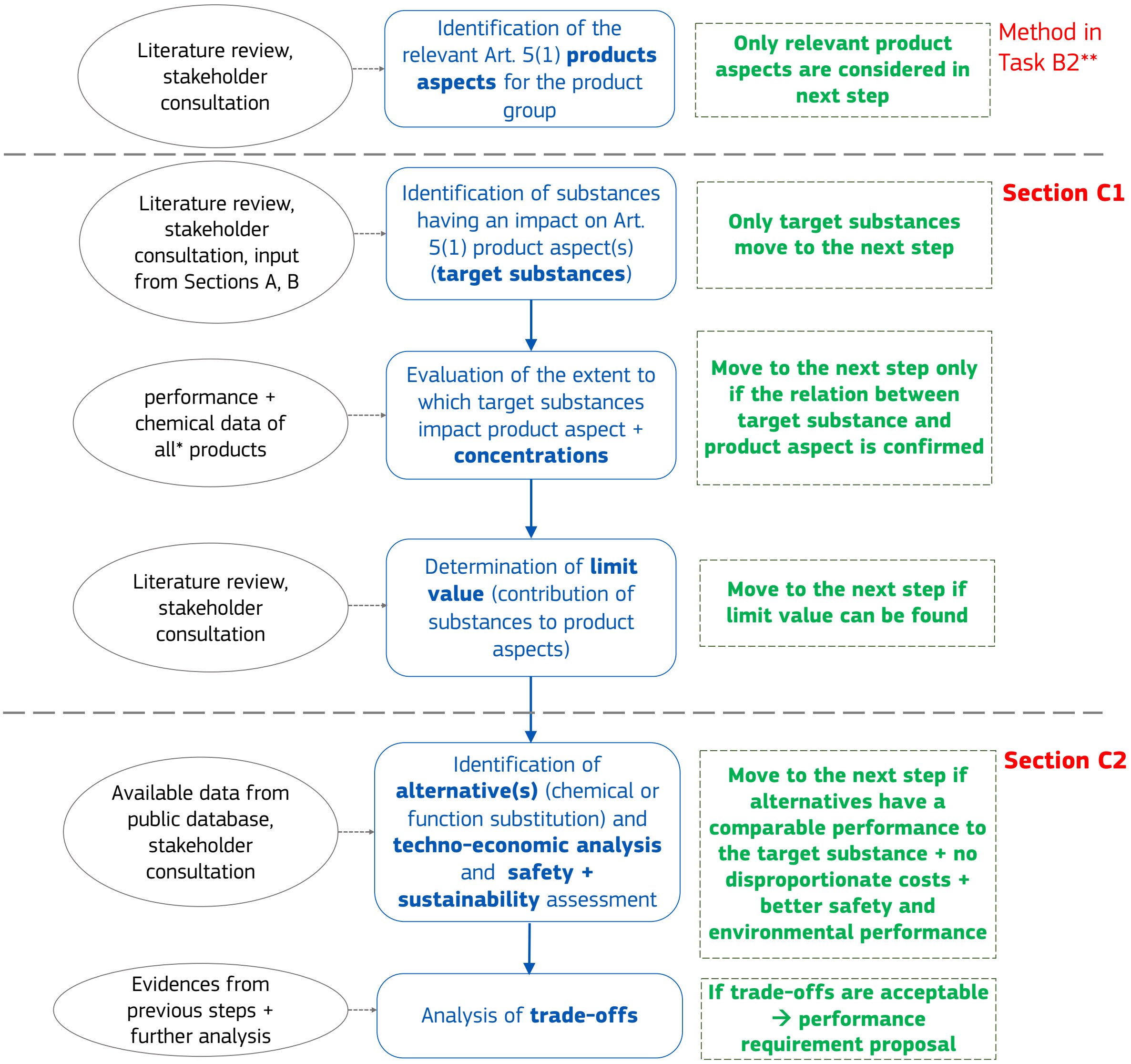
- analysing and proposing thresholds;
- considering potential derogations, where justified;
- potential postponement, or phasing in over time for product or chemical subgroups, of the entry into force of information requirements on SoCs related to a product, where justifiable.

<u>Performance requirements– Section C.</u>

Additional work carried out under Task 6 of the MEErP is the development of potential performance requirements - this is outlined in **Section C.** Performance requirements could take the form of specific restrictions on substances, ranging from a complete ban, limitations on concentration (%w/w) or conditions of use, considering the ESPR product aspects of Art. 5(1). Performance requirements may apply to substances present in the product or in its life cycle, as specified in **Article 6 of the ESPR**. Performance requirements on substances are not set under the ESPR for reasons relating primarily to chemical safety, in order to avoid regulatory overlap with other EU legislation (*inter alia* REACH, CLP, etc). However, where appropriate, ESPR requirements related to SoCs could be proposed where their necessity is related to other sustainability reasons.

Section C1 presents a method for **developing performance requirements** for substances. **Section C2** describes a method for the preliminary **evaluation of alternatives** for substances. It is necessary to undertake the steps in the Section C2 method, in order: (i) to determine if suitable alternatives are available; and (ii) to prevent regrettable substitution(s) being promoted, potentially derived from the possible substance performance requirements being considered (see **Figure II**).

Figure II. Method for developing performance requirements on substances.



* All products for which data can be retrieved, not only Base Case and/or pseudo-worst-case approach.
** Task B2 'Method for the assessment of circularity aspects and integration in or relation with the Method for the Ecodesign of Energy-related Products (MEErP)'.

Source: JRC's own elaboration.

Performance requirements on the presence of substances in products and/or over their life cycle have the aim of improving one or more of the **product aspects mentioned in Art. 5(1)** of the ESPR, such as durability, reliability, reusability. Given the complexity of the interaction of different product aspects, designing performance requirements can be a challenging task. It is therefore recommended to proceed via the following steps:

— Step 1: Identify **the product aspects** relevant for the product group under analysis (this is carried out in Task 4 of the MEErP. For details, see the separate ESPR methodology report in Task B2 ('Method for the assessment of circularity aspects and integration in or relation with the Methodology for the Ecodesign of Energy-related Products (MEErP)'). It is also necessary to integrate the consideration of these Task 4 MEErP aspects with the further analyses for other product aspects, including substances, as described above.

- Step 2: Identify substances (referred to as **target substances**) suspected of having an impact on the relevant product aspects identified).
- Step 3: Establish the **relationship between the concentration or input amount of the target substances and the product aspect(s)** under investigation (for product aspect (o), via the link addressed between the LCI and the LCIA). If no such relationship can be established, this should be clearly stated. In a simplified broader approach as described above, information on relevant substances used along the life cycle of the product under study may be missing, thereby limiting the possibility to perform a full LCA for the analysis of product aspect (o).
- Step 4: Determine the **limit value** that has a significant contribution of the substances to the product aspects under investigation. This limit value is based on evidence gathered from stakeholders, as well as literature regarding defined amounts/concentrations of substances that have negative effects on product aspects and environmental footprint results, whose technical feasibility has been assessed in the Preparatory Study.
- Step 5: To be carried out whenever a performance requirement proposed for a substance could result in a restriction, that in turn could negatively affect – or prevent - the full delivery of its functionality. If this is the case, alternative substances must be assessed to determine, to the extent practicable, whether imposing the proposed limitation is technically feasible, and whether it would be environmentally beneficial and proportionate from the economic point of view (see Section C2).
- Step 6: Where the evaluation of alternatives concludes that suitable alternatives exist, propose a **performance requirement** for the target substance.

The Preparatory Study team should investigate any link(s) between the use(s) of substances and the aspects in Art. 5(1). To facilitate this assessment, the grouping made in Annex I to the ESPR should be used, thus analysing some product aspects in combination and/or taking into account the product parameters cited in Annex I.

Wherever possible, the Preparatory Study team should describe the relationship between relevant substances and related product aspects, at least in a qualitative manner and described in the product's Preparatory Study. Presenting and describing such cases will only be possible if published/verifiable information on this relation has been obtained via **stakeholders from, for example, industry, academia and/or other research organisations and expert stakeholders.**

Section 5.1.1 gives some **examples** of substances affecting the product aspects across different sectors/products. Such an analysis should be performed **on one product aspect at a time**.

The identification of **target substances** is triggered by the comparison of the concentration of the substances in the Base Case(s), i.e. c_{BC} (defined in Section A for functional substances and for non-intentionally added substances), with the identified tentative limit values (i.e. $c_{BC} \geq c_{limit}$), with respect to whether specified product aspects would be affected. As a general indication, the **decision to propose a performance requirement on a substance** (e.g. a limit value) will depend on:

- the impact of the substances on the product aspect concerned;
- the product group under investigation and to what extent such action is expected to provide a significant overall benefit in terms of its environmental performance.

To adequately determine the above, and to formulate a proposal for performance requirements, it is highly desirable that representative data are available for the Preparatory Study.

When performance requirement(s) are considered, **the alternatives** should be evaluated, with regard to the substance(s) proposed for restriction. This allows the Preparatory Study team to verify that suitable alternative(s) exist on the market. The evaluation of alternatives is solely suggested for those cases where **a complete ban is proposed, or a threshold is considered that could negatively affect or prevent the delivery of the functionality of the target substance** along the life cycle stages of the product.

The analysis of the **functional requirements** of the target substance shows the path towards evaluating possible alternatives. The alternative may be an alternative substance (**chemical substitution**) or an alternative solution (**functional substitution**), substituting the function that the existing substance provides in its end-use. In the latter case, the alternative may entail the use of no (substitute) substances at all, for example by redesigning the process or using an alternative technology or technique. **Section C2** provides additional information for undertaking this analysis.

The method proposed for the evaluation of alternatives comprises a preliminary consideration of data quality, followed by three steps:

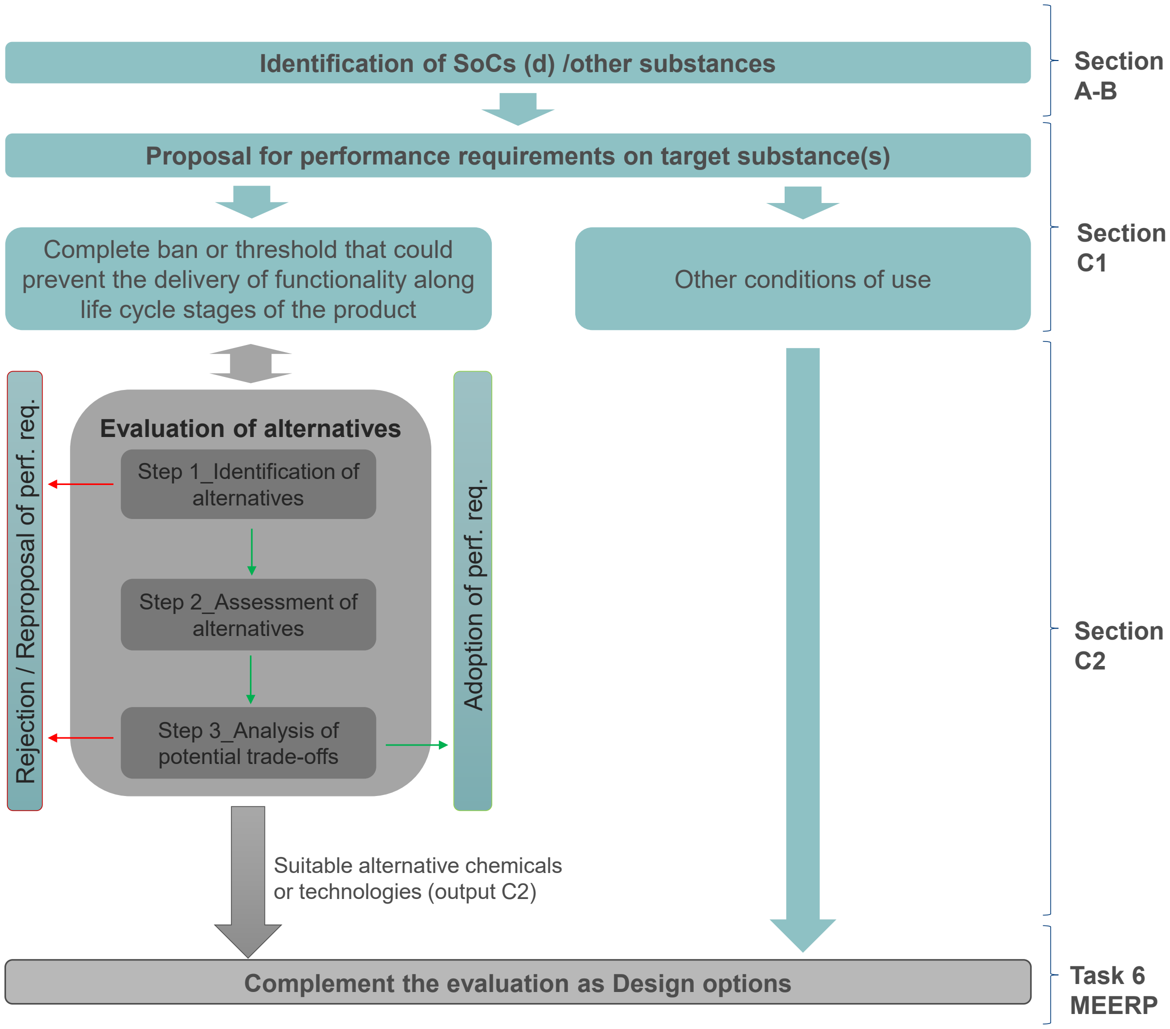
- Step 1 → Identification of alternatives (analysis of functionality, technologies and cost).
- Step 2 → Assessment of alternatives (safety and sustainability).
- Step 3 →Analysis of potential trade-offs.

The outcome of the assessment has the following implications:

- Where a suitable alternative cannot be identified, it follows that it is not feasible to propose the performance requirement being contemplated (following the assessment explained in Section C1). Therefore, the proposal needs to be revised via one or more iterations of the Section C1 method, or ultimately it may be discarded (i.e. no performance requirement(s) would be proposed).
- Where a suitable alternative is identified and is available, the performance requirement(s) being considered following the method in Section C1 may be proposed. In the MEErP Task 6, "Design options", the evaluation of suitable alternative(s) may then be complemented by taking into consideration all the other relevant product aspects.

Figure III summarises the main elements of the assessment, namely the assessment of alternatives and the recommended steps in this methodology report, and how these elements are connected with one other.

Figure III. Structure of the assessment for evaluation of the alternatives and connection with other sections of the ESPR methodology and with the MEErP.



Source: JRC's own elaboration.

Task 6 should address the **verification method** of ESPR information and/or performance requirements on substances. **Section D** identifies the information and/or exemptions to be included in the Digital Product Passport (DPP) and/or other related systems (e.g. EPREL for energy-related products), as they relate to substances (see Section D1). Section D2 discusses the appropriate verification mechanisms for the information and performance requirements regarding substances.

As specified in the ESPR text, the DPP and other related systems are to be used to track information on SoCs. It is suggested that the Preparatory Study team provide the reasoning and a recommendation on the system to be used.

Task 7: Scenarios.

No additional steps proposed.

Some final reflections show a description of the main steps proposed within the method to develop information requirements and performance requirements on substances occurring over the life cycle of products.

In particular, **Figure IV** below presents a summary of the suggested method in this report (also called 'Task B5') including Sections A, B and C. It is important to note that the figure does not report all the additional tasks suggested in the overall ESPR methodology, e.g. complementary analyses to properly address substances for setting ecodesign requirements. **Figure IV** focuses on the different types of substances that could be present in the life cycle of the Base Case, according to their possible identification as SoCs under Art. 2(27), and the proposed approaches to define information and performance requirements.

In **Section A**, all the substances (i.e. intentionally or non-intentionally added to the product, as well as all substances used and/or emitted in the life cycle processes) should be identified and quantified, to the extent possible, along the life cycle stages of the Base Case. Concentrations of substances in the Base Case (c_{BC}) and amounts (or concentrations, depending on the available data) of input/output substances for each life cycle stage (c_{LC}) should be identified and quantified by the Preparatory Study team. However, if a simplified approach is followed, the focus would typically be on identifying only those substances that are intentionally added to the product.

In **Section B**, substances are scrutinised to determine whether they meet the criteria to be identified as SoCs. SoCs under Art. 2(27) (d) are defined considering technical constraints (related to process- and quality-disturbing SoCs) and regulatory and customer chain limitations. Thresholds triggering tracking are proposed for each type of SoC. Section B uses the inventory built in Section A as the basis for identifying potential substances of concern under Art. 2(27), to understand which SoCs are used in the Base Case and its life cycle, and whether any of them might require a justified exemption from mandatory information reporting requirements. This identification of SoCs should always be confirmed and complemented with feedback from stakeholders through the consultations set up as part of the Preparatory Study development.

The main example scenarios related to substances are summarised in **Figure IV**:

- S1 is a substance in the product and its concentration is determined in Section A. It has been identified as a SoC under Art. 2(27) (a) or (c) (the approach to define information requirements applies equally to both types).
- S2 is a substance in the product, and it has been identified as a SoC under Art. 2(27) (b).
- S3 is a substance in the product, and it has been identified as a SoC under Art. 2(27) (d).
- S4 is a substance in the product, but it has not been identified as a SoC under Art. 2(27).
- S5 is a substance not in the product but which is used along the life cycle of the product and its amount (as input or output to a process in the life cycle stages) is determined in Section A. It has been identified as a SoC under Art. 2(27).
- S6 is a substance not in the product but which is used along the life cycle of the product and its amount (as input or output to a process in the life cycle stages) is determined in Section A. It has not been identified as a SoC under Art. 2(27).

However, this summary is not meant to be exhaustive, nor should it be interpreted in a rigid manner, since for substances in the product input and output amounts should also be determined for each process in the life cycle stages, to the extent possible.

In **Section C**, the proposed tasks aim at identifying the possible limit values as a concentration (or input/output amount) of substances according to their effect on the product aspects listed in Art. 5(1). The identification of target substances (i.e. substances proposed to be restricted) is triggered via the comparison of the concentrations/amounts determined in Section A with the identified limit values that will serve as inputs). These substances and related values should be complemented with extensive literature reviews and stakeholder consultations, as explained previously.

Figure IV. Summary of tasks and approaches to address substances in the Preparatory Study.

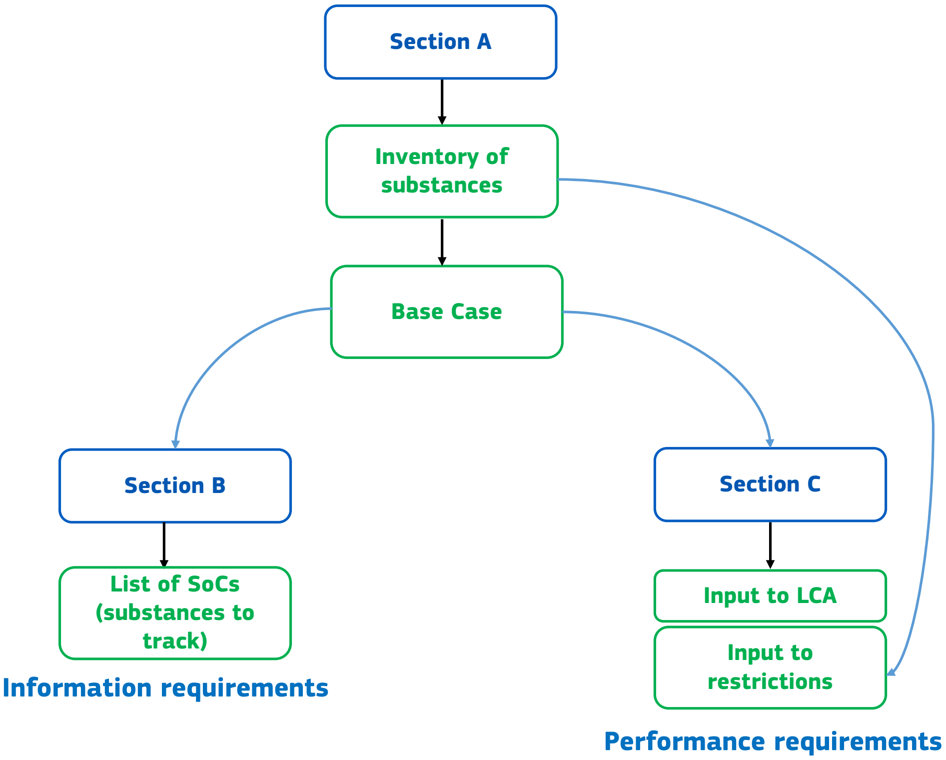
Section Task B5	Task	Types of substances							
A – preliminary steps	Mapping substances along the life cycle of the BC	S_1	S_2	S_3	...	S_4	S_5	...	S_6
	Definition of concentrations in the base case (c_{BC}) and input/output amounts along the life cycle (a_{LC})	c_{1BC}	c_{2BC}	c_{3BC}	...	c_{4BC}	a_{5LC}	...	a_{6LC}
B – definition of information requirements	Identification of SoCs according to Art.2(27)	SoC_a SoC_c	SoC_b	SoC_d		Not a SoC	SoC, not in the product		Not a SoC, not in the product
	Definition of thresholds	0.1% w/w	Substance/ mixtures: Annex II REACH/ Annex I CLP Product: Table 1.5. GHS	C_{alert} for technical constraints C_{alert} based on regulatory and customer limits		/	case by case		/
C – definition of performance requirements	Identification of: • link between substances concentrations/amounts and product aspects (Art. 5(1)) • limit values (c_{limit} or a_{limit}) towards product aspects (**not for safety reasons**) • target substances	c_{1BC} vs c_{limit}	c_{2BC} vs c_{limit}	c_{3BC} vs $c_{alert(technical)}$ c_{3BC} vs c_{limit}	...	c_{4BC} vs c_{limit}	a_{5LC} vs a_{limit}	...	a_{6LC} vs a_{limit}

Source: JRC's own elaboration.

Notation used: $S_{1, 2, ..., i}$: "substance 1" etc.; $C_{1, 2, ..., i, BC}$: "concentration of substance 1 in the Base Case", etc.; $a_{1, 2, ..., i, LC}$: "amount of substance 1 in the life cycle", etc.

Additionally, **Figure V** graphically shows the links of Section A with Sections B and C of the proposed method. While Section A aims to develop an inventory of substances related to the product group under study to build the Base Case, Section B will use those substances listed in the Base Case to identify information requirements, i.e. the substances of concern subject to tracking. The list of SoCs should be used as the input for the LCA of the Base Case(s) and as the preliminary input for the identification of potential restrictions, i.e. performance requirements. In addition, the inventory of substances could also serve as a source of potential performance requirements in substances, and in particular regarding substances of concern in products.

Figure V. Summary of interlinkages of the work to be developed under each proposed section in the Task B5 method.



Source: JRC's own elaboration.

In conclusion, the intention of the combined sections of the method proposed in this report is to assess substances in products and, to the extent possible, along the life cycle of products within the scope of the ESPR. The ultimate objective of the method is to support the possible proposal of ***information requirements*** and ***performance requirements***. The method provides relevant guidance for methodological choices at each stage of the related Preparatory Study Tasks.

The method was tested and refined in a case study, which also served to validate its fitness for purpose (Annex VI).

Finally, it should be emphasised that the work presented in this report is part of the scientific support of the JRC in the development of a methodology to support the implementation of ESPR product-specific delegated acts, as a whole (included in a series of 12 JRC Science for Policy Reports that address different methodological aspects). This methodology to evaluate substances, and substances of concern in particular, will need to be combined and integrated with reports from other studies that are being carried out in parallel, in order to build the final ESPR Methodology for the evaluation of products and definition of ESPR ecodesign requirements. The other JRC Science for Policy Reports from (Tasks B1 to B12) are available at the JRC Publications Repository[3]. Looking to the future, the whole methodology may have to be progressively refined in the light of experience, following its application to a number of product groups, and updated as further data become available, as feasible and as necessary.

[3] JRC Publications Repository.

1 Introduction

Following a Commission proposal[4] of 30 March 2022 for a Regulation on the Ecodesign for Sustainable Products, with the aim of improving the environmental sustainability and the circularity of products placed on the market in the EU, the co-legislators adopted the **Ecodesign for Sustainable Products Regulation** (hereafter ESPR)[5] on 13 June 2024. The Regulation entered into force on 18 July 2024.

The ESPR is based on the success of the **Ecodesign Directive**, whose main focus is to improve the energy use of those energy-related products with a large energy consumption during the use stage, e.g., washing machines and dryers, dishwashers, electronic displays, and light sources, as well as reducing related resource use (*via* enhanced water efficiency, greater product repairability, etc.). It is estimated that by 2030, ecodesign measures for energy-related products will bring energy savings of approximately 230 million tonnes of oil equivalent (Mtoe), cost savings of up to €285 per year for consumers, and extra revenues of €66 billion for European companies[6].

The ESPR **expands the scope** of the Ecodesign Directive to cover, in principle, all products on the European market, with the exception of food and feed, living plants, animals and microorganisms, products of human origin, veterinary and medicinal products, products of plants and animals relating directly to their future reproduction and aspects related to vehicles covered by other sector-specific legislation[7]. The ESPR does not only target the energy consumption of products, expanding the focus to cover the full environmental sustainability of products throughout their life cycle, with special attention to products' circularity aspects. The ESPR envisages the possibility to set **performance and information requirements**. In particular, **Article 5(1)** of the ESPR lists the product aspects that should be addressed by Ecodesign requirements:

(a) durability;

(b) reliability;

(c) reusability;

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[4] COM(2022) 142 final. Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52022PC0142

[5] Regulation (EU) 2024/1781 of the European Parliament and of the Council of 13 June 2024 establishing a framework for the setting of ecodesign requirements for sustainable products, amending Directive (EU) 2020/1828 and Regulation (EU) 2023/1542 and repealing Directive 2009/125/EC. Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32024R1781&qid=1719580391746

[6] European Commission, About the energy label and ecodesign.

[7] For vehicles as referred to in Article 2(1) of Regulation (EU) No 167/2013 of the European Parliament and of the Council (Regulation (EU) No 167/2013 of the European Parliament and of the Council of 5 February 2013 on the approval and market surveillance of agricultural and forestry vehicles (OJ L 60, 2.3.2013, p. 1)), in Article 2(1) of Regulation (EU) No 168/2013 of the European Parliament and of the Council (Regulation (EU) No 168/2013 of the European Parliament and of the Council of 15 January 2013 on the approval and market surveillance of two- or three-wheel vehicles and quadricycles (OJ L 60, 2.3.2013, p. 52)) and in Article 2(1) of Regulation (EU) 2018/858 of the European Parliament and of the Council (Regulation (EU) 2018/858 of the European Parliament and of the Council of 30 May 2018 on the approval and market surveillance of motor vehicles and their trailers, and of systems, components and separate technical units intended for such vehicles, amending Regulations (EC) No 715/2007 and (EC) No 595/2009 and repealing Directive 2007/46/EC (OJ L 151, 14.6.2018, p. 1).), in respect of those product aspects for which requirements are set under sector-specific Union legislative acts applicable to those vehicles. Those vehicles are subject to several product-specific requirements and different harmonised type-approval systems under legal Union acts, such as Directives 2000/53/EC (Directive 2000/53/EC of the European Parliament and of the Council of 18 September 2000 on end-of life vehicles (OJ L 269, 21.10.2000, p. 34)) and 2005/64/EC (Directive 2005/64/EC of the European Parliament and of the Council of 26 October 2005 on the type-approval of motor vehicles with regard to their reusability, recyclability and recoverability and amending Council Directive 70/156/EEC (OJ L 310, 25.11.2005, p. 10)) of the European Parliament and of the Council and Regulation (EU) 2018/858. Additional harmonised requirements for vehicles should be limited to aspects that are not currently addressed, for example environmental requirements for tyres. E-bikes and e-scooters should, however, not be excluded from the scope of this Regulation.

(d) upgradability;

(e) repairability;

(f) the possibility of maintenance and refurbishment;

(g) the presence of substances of concern;

(h) energy use and energy efficiency;

(i) water use and water efficiency;

(j) resource use and resource efficiency;

(k) recycled content;

(l) the possibility of remanufacturing;

(m) recyclability;

(n) the possibility of recovery of materials;

(o) environmental impacts, including carbon and environmental footprint;

(p) expected generation of waste.

Since the ESPR is a framework Regulation, the relevant Ecodesign requirements for individual product groups are to be set in product-specific **delegated acts** (DAs). To this end, the so-called **Preparatory Studies**, should analyse the product aspects listed above, for individual product groups, with the aim of feeding into the development of relevant Ecodesign requirements. Under the current Ecodesign Directive (on Energy-related Products, hereafter ErP), Preparatory Studies are carried out based on the **Methodology for the Ecodesign of Energy-related Products** (hereafter, MEErP).

The present report takes the MEErP as a starting point, expanding it with a suggestion for <u>*a method to address the presence or use of substances*</u> impacting on any of the product aspects listed above, both with respect to information requirements and performance requirements.

Article 2(27) of the ESPR defines substances of concern (hereafter, **SoCs**) as it follows:

'Substance of concern' means a substance that:

a) meets the criteria laid down in Article 57 of Regulation (EC) No 1907/2006 and is identified in accordance with Article 59(1) of that Regulation;

b) is classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 in one of the following hazard classes or hazard categories:

(i) carcinogenicity categories 1 and 2;

(ii) germ cell mutagenicity categories 1 and 2;

(iii) reproductive toxicity categories 1 and 2;

(iv) endocrine disruption for human health categories 1 and 2;

(v) endocrine disruption for the environment categories 1 and 2;

(vi) persistent, mobile and toxic or very persistent, very mobile properties;

(vii) persistent, bioaccumulative and toxic or very persistent, very bioaccumulative properties;

(viii) respiratory sensitisation category 1;

(ix) skin sensitisation category 1;

(x) hazardous to the aquatic environment - categories chronic 1 to 4;

(xi) hazardous to the ozone layer;

(xii) specific target organ toxicity – repeated exposure categories 1 and 2;

(xiii) specific target organ toxicity – single exposure categories 1 and 2;

c) is regulated under Regulation (EU) 2019/1021; or

d) negatively affects the reuse and recycling of materials in the product in which it is present;

This document includes several **Annexes** namely "Terminology", "Regulatory background", "Existing approaches to address substances in products" and "Approach to data modelling for the worst-case scenario in Section A". **Annex I** on "Terminology" provides an overview of the relevant definitions for this study, and therefore for the future Preparatory Studies to be developed under the framework of the ESPR. **Annex II** relates to "Regulatory background" reviews and presents a wide variety of legal documents, as well as other instruments, schemes and standards, that are relevant for establishing a method for the setting of information requirements on substances of concern and performance requirements on substances (for reasons other than chemical safety, see table in Annex II). **Annex III** provides a summary of selected relevant studies addressing the identification, tracking or restriction of substances in products. The methodologies or studies presented in this annex are important in order to have an overview of how substances have been addressed in the past in different product policy contexts, e.g. the Ecodesign Directive and the EU Ecolabel Regulation, both of which were of inspiration in developing and applying the current method under the ESPR. **Annex IV** provides further details about the approach to data modelling, precisely about the consideration of a Base Case based on a worst-case scenario. Annex IV also guides on how to perform a representativeness check and uncertainty analysis on the substances considered. **Annex V** proposes a questionnaire for stakeholders to request information on substances and to be used during the development of the Preparatory Study (PS). Additionally, **Annex VI** includes a case study aimed to test the method on a specific product group relevant for ESPR, i.e. apparel textile products (clothing).

1.1 Objectives of the study

Given that ecodesign requirements will be set[8] for different product groups that will be prioritised under the ESPR, there is a need for a common method that defines how to set information and performance requirements on the presence of substances, and in particular of substances of concern (SoCs) in products[9].

The present report thus develops a method which should serve as a basis to **identify and inform about the presence of SoCs** throughout the life cycle of the products concerned (i.e. in the form of information requirements) as well as to provide **a decision process for the restriction of product-specific substances** (i.e. in the form of performance requirements), as outlined in **Figure 1**.

Note that within this method, reference to "performance requirements and information requirements" indicates <u>*performance requirements and information requirements for substances in products and present along the life cycle of the product*</u> as e.g. emissions, so as appropriate, the output of the application of this method would be the development of "product performance requirements and product information requirements for substances".

[8] After a Preparatory Study the decision to take can also be to not set any ESPR requirements.

[9] 'Product' is defined in ESPR as "any physical goods that are placed on the market or put into service". Note that when products are generically mentioned in this report, it is meant to include **final products, components and intermediate products.**

In a simplified approach, information requirements would only relate to intentionally added substances remaining in the products under assessment. Performance requirements would refer to the use of substances impacting products aspects in Art. 5(1), and the use of substances of concern (as in product parameter (f), Annex I)

This report only addresses the presence of substances and substances of concern within the **scope of the ESPR**.

Firstly, this report addresses the definition of **information requirements** in order to enable the tracking of SoCs (a, b, c and d) throughout the life cycle of the products concerned as defined in **Article 2(27)** of the ESPR. The SoCs considered should be those present in the product, (including once the product becomes waste and is recycled into a recycled product – i.e. recyclate – as a result of the previous life cycle stages and waste management operations) as well as those which are used along the preceding steps of the product's use phase but which do not remain in the product (e.g. emissions). The presence of SoCs should be assessed also for recycled materials present in the product under analysis. This will enable the necessary flow of information between businesses, organisations, consumers and waste management operators (recyclers, preparation for reuse, etc.) *via* the digital product passport (DPP) or other systems such as labels, tags, etc.

Secondly, this report addresses product **performance requirements** concerning the presence or use of substances, which include restrictions of substances for reasons other than chemical safety. The restrictions are envisaged to be mainly product-oriented (i.e. concerning substances in the product); however, substances along the life cycle and not remaining in the product could potentially also be subject to performance requirements, as for instance if associated to emissions related to the use of a substance or associated to high environmental impact, such as those reported in a carbon footprint, e.g. for their production. Thereby, performance requirements will focus on the 'product aspects' listed in **Article 5(1)** such as durability, resource use, possibility of recycling, possibility of remanufacturing, environmental footprint, etc., to the extent that a causal link or a synergy can be found between these and the presence or use of a substance, with emphasis on the use of substances, and in particular the use of substances of concern (product parameter **(f) in Annex I** of the ESPR).

More specifically, the method for **information requirements** focuses on how to track SoCs, including a method to identify the substances defined under Article 2(27) (d) in products, i.e. those that '*negatively affect the reuse and recycling of materials in the product in which it is present*', and including the definition of the appropriate thresholds for the tracking of all SoCs, and relevant exemptions. At the same time, the method for **performance requirements** should help to determine whether restriction measures for substances would be feasible and appropriate for a given product group, and to define the appropriate restriction conditions, including concentration thresholds and relevant exemptions. The setting of performance requirements should also not worsen the technical, safety and sustainability aspects of the product.

In addition, the method takes into account that whenever a restriction proposed on a substance consists of a complete ban, or a threshold that could prevent the delivery of its functionality along the life cycle stages of the product, the available information on the profiles of the alternative(s) should be investigated and evaluated. This should be performed both from the technical point of view and from the safety and sustainability perspective. In this specific situation, where *no suitable alternative is available*, the performance requirement <u>*cannot*</u> be proposed (see section C2 for a detailed discussion). While safety information might be easier to gather from existing chemical safety assessments performed by the relevant Union bodies, it is acknowledged that finding detailed information related to the sustainability profile might be quite challenging.

Different frameworks can be considered in the context of the analysis of the alternatives. The **Safe and Sustainable by Design** framework (SSbD) developed by the Commission[10] may provide the basis for the investigation of the alternatives, with specific regard to the evaluation and comparison of the safety and sustainability aspects of the alternatives tested against the target substance. The SSbD framework, as it currently stands, does not include an assessment of the economic feasibility of potential alternatives. As a valuable contribution to the assessments, the data and guidance available on Analysis of Alternatives (AoA), both from European (e.g. JRC, ECHA) and international bodies (e.g. OECD), should also be considered.

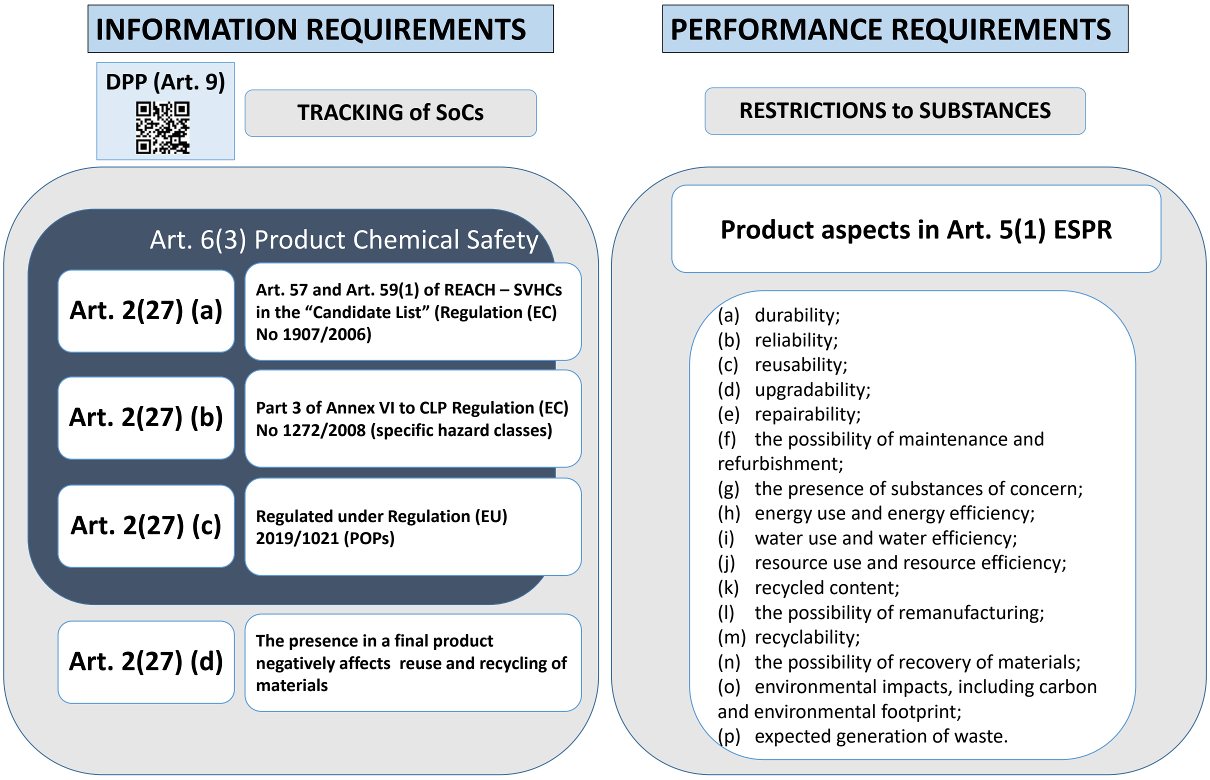
While it is not its primary objective, the establishment of product performance requirements on substances may also reduce significant risks to human health or the environment, as a secondary consequence of any substance-related restriction. Furthermore, the method proposed may contribute to identify and flag hazardous substances that may be relevant for other regulatory measures, for example under REACH and other chemicals legislation. However, the elements that would be required for elaborating such possible regulatory measures are outside the scope of this study.

This study is part of a series of 12 JRC Science for Policy reports that address different methodological aspects for the implementation of ESPR. The other JRC Science for Policy Reports from (Tasks B1 to B12) are available at the JRC Publications Repository[11].

[10] European Commission. (2022a). COMMISSION RECOMMENDATION (EU) 2022/2510 of 8 December 2022 establishing a European assessment framework for "safe and sustainable by design" chemicals and materials. Official Journal of the European Union, 325/179(July 2020). Available at: https://research-and-innovation.ec.europa.eu/system/files/2022-12/Commission%20recommendation%20-%20establishing%20a%20European%20assessment%20framework%20for%20safe%20and%20sustainable%20by%20design.PDF

[11] JRC Publications Repository.

Figure 1. Method concerning the presence and use of substances under the ESPR.



Source: JRC's own elaboration based on the ESPR.

1.2 Structure of the report

The present report is structured as it follows:

1. Introduction – This section provides an overview of the work to be carried out and a general introduction to the main sections of the method. It includes the objectives of the present study and the structure of the report.

2. Interaction between the method on SoCs and the MEErP – This section presents how the Methodology for the Ecodesign of Energy-related Products (MEErP) is used as the basis on which to build additional methodological elements that addresses the identification, tracking and restriction of substances, and in particular SoCs in products. A detailed analysis of how the MEErP considered substances is reported in Annex III.

3. Section A: Preliminary steps for the method – This section explains the preliminary steps that should be performed in the Preparatory Study for a product-specific delegated act prior to the identification of information and performance requirements for substances. In particular, this section explains the interaction of the methodology proposed in the present report with the MEErP.

4. Section B: Method for developing information requirements[12] for substances of concern – This section aims to provide guidance on how to set information requirements referring to SoCs that stay in the product (including the end-of-life scenario and subsequent outputs, e.g. secondary material) and throughout the life cycle of the products concerned (as input and output flows to each life cycle stage). The requirement to track a substance under the ESPR is triggered by

[12] From ESPR: 'information requirement' means an obligation for a product to be accompanied by information as specified in Article 7(2)'https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52022DC0140&qid=1649112555090.

its identification as a SVHC under REACH, its harmonised classification under CLP, if considered a Persistent Organic Pollutant (POP) under the POPs Regulation or by other requirements to be defined as a SoC under Article 2(27) that are to be analysed pursuant to the applicable legislation.

5. Section C: Method for developing performance requirements[13] on substances – This section identifies the approach to be followed to define restrictions on the use of substances under the ESPR. This section focuses on substances that meet the definition of SoCs under Art. 2(27) (d) as well as on other substances that impact directly on the product aspects listed under Art. 5(1) of the ESPR. This is relevant to substances along the whole value chain of the product. This section also addresses the identification and the evaluation of the substitution with alternatives, for those substances for which product performance requirements are proposed.

6. Section D: Information to collect and demonstrate the verification of product requirements on the presence of substances – This section identifies the information and/or exemptions to be included in the Digital Product Passport (DPP) and/or other equivalent systems in relation to substances and also discuss the appropriate verification mechanism which is necessary to ensure compliance with ecodesign requirements on substances, including the type of documentation to be provided to prove the veracity of the information collected and displayed.

7. Conclusions – This section summarises the method proposed in the present report for the identification and tracking of substances of concern in products and for the preparation of restriction measures on the use of substances in products.

Annexes – This study contains several annexes related to the terminology used, the regulatory background, existing approaches to address substances in products and details on data modelling towards building a worst-case scenario and the proposed questionnaire to request information on substances to stakeholders. In addition, a case study on apparel textile products (clothing), is presented in Annex VI.

[13] From the ESPR: 'performance requirement' means a quantitative or non-quantitative requirement for or in relation to a product to achieve a certain performance level in relation to a product parameter referred to in Annex I'.

2 Interaction between the ESPR method on substances (Task B5) and the MEErP

The present report takes the Methodology for the Ecodesign of Energy-related Products (MEErP) as the basis on which to build a method that addresses the identification, tracking and as appropriate, the restriction of substances, in particular of SoCs, in products. This section thus presents the steps which are either defined in the MEErP or are suggested in addition to these, and that should be carried out in an ESPR Preparatory Studies before proposing potential information requirements and performance requirements concerning substances.

The MEErP[14], initially developed under the original Ecodesign Directive 2005/32/EC, evaluates whether and to which extent energy-related products (ErP) fulfil certain criteria that make them eligible for ecodesign implementing measures. The MEErP was originally published in 2005, and then reviewed in 2011 and 2013, and has been used in more than 40 Preparatory Studies for Ecodesign of ErP. The most recent review of the MEErP was published in March 2024[15]. The tasks defined in the MEErP are accompanied by a spreadsheet-based streamlined Life Cycle Assessment open access tool, the **EcoReport tool**. This spreadsheet is completed and revised in an iterative manner, as the MEErP Tasks are progressively completed, using wherever possible primary data, provided by stakeholders and supplemented by literature reviews and questionnaires undertaken during the execution of the product-specific Tasks.

The MEErP focuses primarily on the energy consumption and related resource use of products during the production and particularly the use stages, and is structured in tasks as presented below and in **Figure 2**:

- **Task 0: Quickscan**
- **Task 1: Scope**
- **Task 2: Markets**
- **Task 3: Users**
- **Task 4: Technologies**
- **Task 5: Environment & Economics (Base case LCA & LCC)**
- **Task 6: Design options**
- **Task 7: Scenarios**

Task 0 is an optional task applicable to large or heterogeneous product groups, where it is recommended to carry out a first product screening, with the objective of better identifying which product(s) should be addressed by the Preparatory Study.

Task 1 identifies and defines the scope of the product group, i.e. the products to which the ecodesign measures to be developed would apply.

[14] COWI and VHK, MEErP 2011. Methodology Report – Part 1: Methods, Final Report, Prepared for the European Commission, DG Enterprise and Industry, 2011, NB-03-13-617-EN-C, available at: https://op.europa.eu/en/publication-detail/-/publication/b7650397-32f1-436c-82c4-df39aef297a3

[15] European Commission, Joint Research Centre, Gama Caldas, M., Eynard, U., Spiliotopoulos, C., Blengini, G., Alfieri, F., Mancini, L., Mathieux, F. and Ardente, F., Review of the MEErP - Methodology for Ecodesign of Energy-related Products, Publications Office of the European Union, Luxembourg, 2024, https://data.europa.eu/doi/10.2760/24524, JRC136406. https://publications.jrc.ec.europa.eu/repository/handle/JRC136406.

Task 2 provides the market analysis of the product group under assessment, including the products' apparent consumption in the EU, market and cost inputs for the environmental impacts of the product group, and latest market trends in product design.

Task 3 identifies barriers and restrictions to possible ecodesign measures due to social, cultural or infra-structural factors. This task also quantifies relevant user-specific parameters that can influence the product's environmental impacts during use.

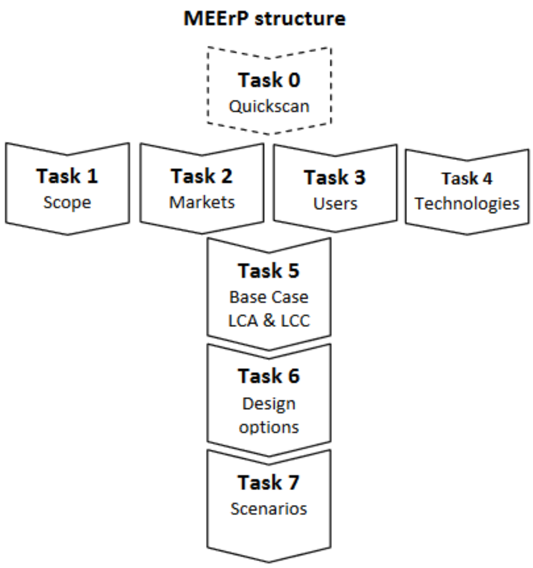
Task 4 entails the technical analysis of products in the EU market, including a description of the existing products up to BAT (Best Available Techniques) and BNAT (Best Not yet Available Techniques).

Task 5 includes the definition of a "Base-case" product based on one or more average EU product(s). This is subsequently used for most of the environmental and Life Cycle Cost analyses that are also carried out within this Task.

Task 6 identifies possible design options, their monetary consequences in terms of Life Cycle Cost for consumers, and their environmental costs and benefits. Design measures are addressed by the Least Life Cycle Costs (LLCC) and the Best Available Techniques (BAT). In particular, the distance between the LLCC and the BAT indicates – where the Least Life Cycle Cost solution is set as a minimum target - the remaining space for product differentiation (innovation and competition).

Task 7 puts together the outcomes of all previous tasks. It analyses suitable policy measures to achieve the improvement potential for the product e.g. implementing the Least Life Cycle Costs design option as a minimum mandatory requirement and Best Available Techniques as a target to be addressed via promotional measures, using legislation or voluntary agreements, labelling, benchmarks and possible incentives. It draws up scenarios quantifying the improvements that can be achieved with respect to a Business-as-Usual scenario and compares the outcomes with EU environmental targets. It makes an estimate of the impact on consumers (purchasing power) and industry (employment, profitability, competitiveness, investment level, etc.). This task also includes a sensitivity analysis of the main parameters to study the robustness of the outcome including, amongst others, those related to energy prices and societal costs.

Figure 2. Structure of the Methodology for the Ecodesign of Energy-related Products (MEErP).



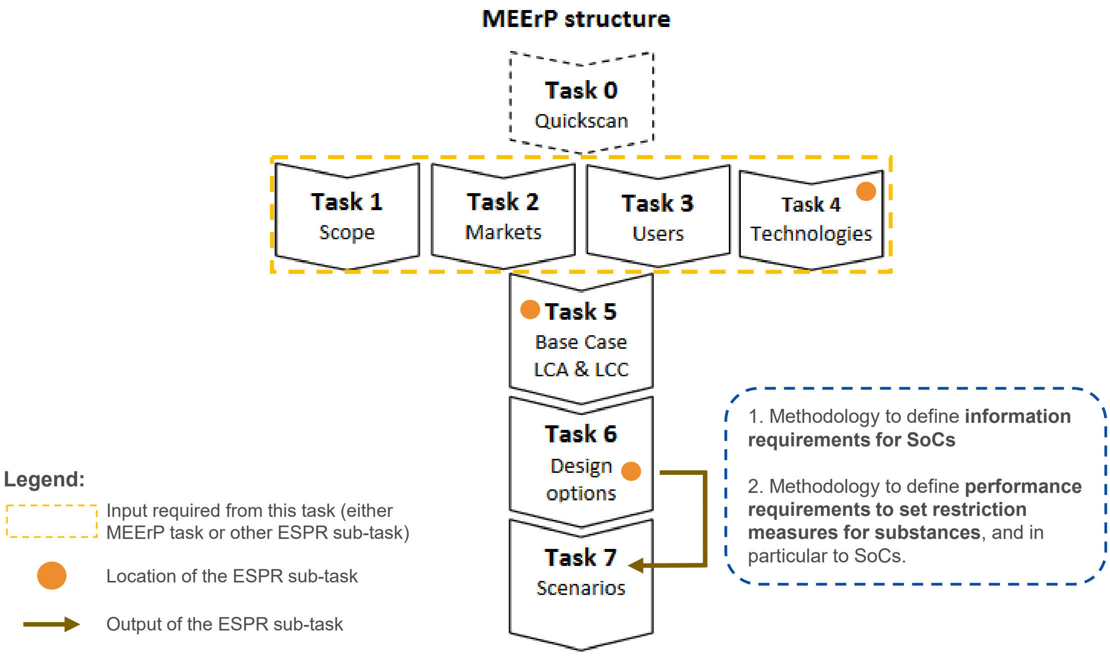
Source: COWI and VHK, 2011.

Tasks 1-4 can be performed in parallel in order to prepare the ground for Tasks 5-7 that follow, which should be performed in sequentially. However, it is worth noting that the experience from pilot projects under development revealed that it is advantageous to perform Task 1 first, followed by Task 2 and 3 which can be performed in parallel and followed by Task 4[16]. Given this, the sequence and approach to the MEErP tasks may need to be adjusted according to the product group under study.

In 2013, the MEErP was supplemented by a module[17] to assess the possibility of enhancing material efficiency aspects of products, in addition to their energy consumption. The additional module identifies four material efficiency parameters to be assessed within Task 2 of the MEErP: namely: recyclability benefit rates, recycled content, lifetime and Critical Raw Material Index. The revision of the MEErP in 2024 updated the EcoReport Tool.

Figure 3 outlines the main Tasks of the MEErP that need to be expanded in order to include insights of relevance for the methodology on substances, as well as the outputs that are expected from the inclusion of the methodology on substances in the MEErP.

Figure 3. Interaction between the MEErP and the methodology on SoCs presented in this report.



Source: JRC's own elaboration adapted from COWI and VHK, 2011.

16 Delre et al., 2024, Preparatory study on textiles for product policy instruments: Ecodesign, EU Green Public Procurement, EU Ecolabel, 1st milestone, JRC.

17 BIO Intelligence Service, 2013, Material-efficiency Ecodesign Report and Module to the Methodology for the Ecodesign of Energy-related Products (MEErP), Part 1: Material Efficiency for Ecodesign – Final Report to the European Commission - DG Enterprise and Industry, NB-04-13-155-EN-N. Available at: https://op.europa.eu/en/publication-detail/-/publication/7c3d958d-42cc-4af7-985c-2a3347b66fa8.

Box 1. The interaction between the MEErP and the ESPR method on substances and substances of concern (Task B5).

This report proposes a method for defining possible performance requirements on the use of substances and the identification and tracking of substances of concern, to be integrated within the MEErP. This method includes different steps that are to be performed in the various Tasks of the MEErP. Preliminary steps include the gathering of data on substances, to be finalised before the end of Task 4 of the MEErP, as well as in the building of the Base Case, to be performed at the beginning of Task 5 of the MEErP (see Section A). Moreover, this methodology presents the steps to be performed in Task 6 of the MEErP to define information requirements for substances of concern (see Section B) as well as performance requirements for substances, and in particular to substances of concern for reasons other than safety (see Section C).

2.1 How are ecodesign requirements put forward?

As specified in the MEErP and in a manner consistent with the requirements of the Commission's Better Regulation Guidelines, ecodesign measures and/or requirements are proposed following a procedure involving consultation of stakeholders, which can overall last typically up to around 4 years. Priority product groups are defined based on their potential for cost-effective contribution to achieving Union climate, environmental and energy efficiency objectives and are subsequently defined in a working plan, pursuant to Article 18 of the ESPR, which is adopted by the Commission, following consultation of the Ecodesign Forum. This working plan defines the priorities for the development of ecodesign delegated acts under the ESPR. Generally, inclusion in this working plan triggers the initiation of a product-specific Preparatory Study.

The PS involves extensive technical discussions with interested stakeholders and is undertaken by the Commission itself (usually the JRC) or by an independent consultant, in close consultation with DGs ENV, GROW and ENER.

The **PS development** is divided in a series of steps as follows, typically lasting about 2 years (please note that the process may be adjusted to the particular PS under development):

- A **preliminary stakeholder questionnaire** is published to establish an interested stakeholder base and to collect initial information.
- A **first stakeholder meeting** is organised where the work on Task 1 of the MEErP and preliminary work on Tasks 2-4, is discussed. This meeting involves publication of the Task 1 work in advance and a period of consultation after the meeting.
- A **second stakeholder meeting** is organised where the work on Tasks 2-4 of the MEErP is presented and discussed. As in the previous meeting, a report containing the development of Tasks 2-4 of the MEErP before the meeting and consultation is open for a certain time after it.
- A **third stakeholder meeting** takes place where the work on Tasks 5-7 of the MEErP is discussed followed by consultation. Potentially, a fourth (and final) stakeholder meeting may be required, to specifically discuss Task 7 and aspects specific to the Digital Product Passport.

Based on the Preparatory Study, the Commission will work on the development of an ***Impact Assessment Staff Working Document***, subject to the requirements under the Better Regulation Guidelines and on the development of a first draft delegated act proposing product-specific ecodesign measures. The latter will be discussed in the *Ecodesign Forum*[18] (an expert group of Member States and stakeholders' representatives) established under the ESPR. The impact

[18] Commission Decision (EU) 2024/2779 of 24 October 2024 setting up the group of experts on ecodesign for sustainable products and energy labelling (the Ecodesign Forum) http://data.europa.eu/eli/dec/2024/2779/oj.

assessment development process includes consultation of stakeholders on the envisaged measure via a "call for evidence" and, generally, a concurrent public consultation[19], which is published in the 'Have Your Say' portal[20] for a period of 12 weeks.

Following consultation of the draft delegated act between Commission services and in parallel or following further discussion in the Ecodesign Forum, the draft delegated act is subjected to further feedback from stakeholders via the 'Have Your Say' webpage of the Commission for a period of 4 weeks. In parallel to this, additional feedback is requested via the Technical Barriers to Trade Notification, under World Trade Organisation agreed rules, for a period of 60 – 90 days. The final draft delegated act can be subsequently adopted by the Commission and be notified simultaneously to the European Parliament and to the Council. The co-legislators may object to the measure within a period of two months after notification, which can be extended by another two months at the request of either of them. In the absence of any objection, the act is adopted and published in the Official Journal of the European Union.

Further information to complement this section is included in the report of Task B10 of the ESPR methodology ('Method for the integration of the support to ESPR impact assessments within the evaluation process of products, including international trade aspects and impact of measures on third countries'[21]).

[19] See Tool #51 "Consulting Stakeholders" of the European Commission's Better Regulation Toolbox.

[20] Have your say portal. https://ec.europa.eu/info/law/better-regulation/have-your-say_en.

[21] Arcipowska A., Blanco-Perez S., Method for the integration of the support to ESPR impact assessments within the evaluation process of products, including international trade aspects and impact of measures on third countries, Publications Office of the European Union, Luxembourg, 2025, JRC142690.

3 Section A: Preliminary steps for the method

In order to set information requirements on SoCs (Section B of the present method) and performance requirements (Section C of the present method) concerning substances for reasons other than chemical safety, as prescribed by Art. 6(3) of the ESPR, it is essential to have a deep understanding of the value chain of the product under assessment as well as of the product's material composition, as also specified in the MEErP. While the MEErP tackles these aspects in its Task 4 ('Technologies') and Task 5 ('Base Case'), it does not focus on specific substances used in the product or in its value chain. Indeed, ecodesign requirements under the Ecodesign Directive typically did not address the presence of substances in such depth as the ESPR prescribes, and they just require the identification of those components in which critical raw materials (CRM) were present, and from which these CRM could then be recovered at the End-of-Life management stage, or where (for example) brominated flame retardants were present (thus hindering recycling). Overall, the principal aim of the 2009 Ecodesign Directive was reducing energy, water and resources consumption during the use phase.

This section thus presents the steps that should be performed by the developers of Preparatory Studies (hereafter the 'PS team'), in addition to what is already envisaged under the MEErP, in order to obtain a good understanding of the product group, its material and chemical composition, and its life cycle, enabling the setting of potential information requirements and performance requirements concerning substances, addressing both intentionally and non-intentionally added substances. This assessment is to be carried out via prioritising information on substances remaining in the product. Substances, particularly substances of concern, used during manufacture and emitted along the life cycle, which may not remain in the product, should also be examined and discussed, to the extent allowed by available information and a proportionate use of study resources.

Two approaches can be followed for data collection: (1) all substances, particularly substances of concern, used during product manufacture and emitted along the life cycle of the product; and (2) a simplified approach, limited to intentionally added substances remaining in the product

3.1 The Base Case

As prescribed in the MEErP, the PS team should, on the basis of the information gathered in Tasks 1-4, define the Base Case(s) for the product group under analysis (Task 5). The Base Case(s) is then used as a reference for performing a hotspot analysis of its environmental impacts, which would be the basis for developing and testing ecodesign requirements in Tasks 6 and 7.

According to the MEErP, the Base Case is "**the average product on the EU market in terms of resource efficiency, emissions and functional performance. […] The Base Case may or may not be a real product that one can buy on the market**. Especially when the market is made up of different technologies, the Base Case will be a virtual (non-existing) product with the average sales-weighted characteristics of all technologies around. On the other hand, e.g. if the market and technical information is incomplete, the analysts of the Preparatory Study, in consultation with stakeholders and the Commission services may decide to choose a real product for which there is a consensus that this would represent 'the average'".

It should be noted that the definition of the Base Case in the MEErP is very similar to the definition of 'representative product' given in the Product Environmental Footprint Category Rules (PEFCRs) Guidelines[22].

When the product group under study presents a significant heterogeneity of functions, compositions and/or technologies, the MEErP foresees the possibility to develop more than one Base Case for the product group.

The MEErP includes a discussion on whether the Base Case should be based on a worst-case product rather than on the EU market average product. Whilst the MEErP acknowledges that there could be design options for which a worst-case would be useful, i.e. for recyclability, it however concludes that using an EU-average product as a basis for possible requirements is already a reasonably ambitious starting point, since the aim of the ESPR is to "remove the worst performing products from the market and gradually move to the best performing products where that is necessary to contribute to the environmental sustainability objectives".

The PS team should follow the MEErP approach, as it best describes the reality and already constitutes an ambitious analysis. However, data on substances in products is often scarce due to limitations in chemicals information transmission along the supply chain, owing to such information often being claimed as proprietary; it can also be highly uncertain (due to the variability between products on the market). Therefore, defining the chemical composition of the Base Case that fully reflects the EU market average will seldom be possible. Given that the aim of the ESPR is to "remove the worst performing products from the market and gradually move to the best performing products where that is necessary to contribute to the environmental sustainability objectives", it is proposed that the PS team considers a larger variety of substances for the Base Case (compared to a full market average approach), taking into account information from stakeholders as well as evidence found in literature. The approach proposed can be considered as a **worst-case approach**, as it would consider and quantify more substances than the average use of substances in products in the market (i.e. the Base Case), but less than accounting for all possible substances known to be used in products in the market (i.e. the worst case). Given this, the approach can be more appropriately defined as a **pseudo-worst-case approach** given it acknowledges that in most cases it will not be possible to build an inventory or define a base case which accounts for all possible substances relevant to the product group concerned.

In this approach, it is suggested that the PS team analyses the substances used in the product under analysis **in two steps**, firstly defining an **inventory** of the main substances (and their concentration) used in the product and its life cycle, and then secondly, starting from such inventory, **building the Base Case** by relying on representative substances only. The next sections provide a comprehensive description of these steps: Sections 3.2.1 'Product composition' and 3.2.2 'Life cycle stages' for the inventory of substances, and Section 3.3 for building the Base Case. Such an inventory of substances and concentration ranges, where possible, can be used for proposing performance requirements on substances (see Section C).

3.2 Data gathering for the definition of the Base Case

To carry out the product environmental hotspot analysis in Task 5 of the MEErP the Preparatory Study team should carry out a data collection process in order to define the Base Case(s), in terms of material and chemical composition as well as its life cycle stages, in line with the EU average process on the market. This data collection is, in principle, to be included as part of Task 4 'Technologies' of the MEErP, although it can be carried out throughout Tasks 0-4.

22 Product Environmental Footprint Category Rules Guidance, Version 6.3 – May 2018. Available at: https://eplca.jrc.ec.europa.eu/permalink/PEFCR_guidance_v6.3-2.pdf.

Under the MEErP, the definition of the Base Case(s) entails information about its building blocks, i.e. components and materials (Bill of Materials). The ESPR enables and indeed requires an increased amount of information to be gathered, extending it also to substances. Preparatory Studies should thus look into the **components, materials, and substances** present in the product group (and sub-groups) under analysis.

Task 5 of the MEErP includes an environmental hotspot analysis by means of Life Cycle Assessment (LCA) modelling. This implies the research and definition, by the PS team, of the life cycle of the product under analysis, where material, energy and other inputs through the various life cycle stages are modelled to obtain the environmental impact profile of the products included under the scope of the product group. This involves, as prescribed by the MEErP, the identification of the **main life cycle stages** that constitute the value chain of the Base Case(s) (and its sub-groups), from cradle-to-grave, i.e. including the extraction of raw materials, any intermediate stage, the manufacturing of the components, materials and the final product, the placement of the final product on the market, its use by the customer and the end-of-life stages once the product is discarded by the user. Because of different waste management systems across the EU MSs, and the sub-optimal efficiencies of separate waste collection, the definition of the end-of-life stage will likely imply more than one treatment scenario (e.g. reuse, recycling, recovery or disposal). The PS team should also identify, for each of the life cycle stages, the **processes and sub-processes** involved.

For **intermediate products**, the system boundaries of the life cycle to be analysed cannot be from cradle-to-grave, since the intermediate product may have a large number of applications into final products that would not be realistic to model. Instead, the PS team should consider the life cycle of the intermediate product from cradle-to-gate, identifying all processes and sub-processes involved until the placing on the EU market of the intermediate product. This is in line with the PEF methodology, where the distribution, use and end-of-life stages are recommended to be excluded from the life cycle stages. However, where relevant, the PS team could analyse, to the extent possible, the final applications of the intermediate products, in order to further understand the characteristics needed for the intermediate products, especially where there the final applications constitute a limited number of well-known cases, e.g., chromium stainless steel, where corrosion resistance is a priority in the final application. However, it is acknowledged that often this analysis would entail large resources, which may not fit within the scope of the PS.

Given the focus of the ESPR on substances and substances of concern (previously not the principal focus of the Ecodesign Directive), the PS team should develop an **inventory of the substances per function used across the life cycle** of the product group under analysis, to the extent possible, before defining the Base Case.

In fact, ESPR has to "look backwards" (to legacy chemicals) and "look forward" (to the recycling phase) to a greater extent than ErP in Ecodesign has done to date. Thus, there are two debates to have in parallel:

- MEErP vs. Full LCA; and
- "Average Case" vs. "Worst-Case" (including emissions).

In a simplified approach, the data collection process to define the Base Case(s) would generally focus on intentionally added substances that remain in the products under assessment

The use of the MEErP/EcoReport tool compared to a full detailed LCA relates to the degree of complexity of the product and its related whole-life stages, including manufacturing processes and use, as well as data availability and representativeness, to be determined via an initial "hotspots" analysis. The EcoReport tool of the MEErP is the minimum mandatory point of departure regarding the assessment. Another factor to consider is whether a PEFCR is already in existence, how up-to-date and representative it is, and what additional or alternative data may be gathered during the Preparatory Study that is updated, of sufficient quality and representativeness, and that has sufficient acceptance amongst stakeholders, once checked and verified with them during the successive consultation steps built into the ESPR process.

In order to analyse substances in sufficient detail, the use of the **"worst-case" approach rather than the "average case" is suggested**. However, when proposing draft ecodesign requirements resulting from such an analytical approach, these could be defined in the resulting delegated act following a tiered approach (over time) for entry into application of the requirements. Consequently, information or performance requirements could be associated to differentiated dates, thus taking into account the technical, practical and economic feasibility of compliance, allowing a proportionate time for the affected stakeholders to implement the necessary measures to ensure compliance. This approach has already been used in implementing measures adopted under the Ecodesign Directive, for instance in the ecodesign Energy Efficiency Index requirements for electronic displays[23].

Taking inspiration from previous ecodesign regulations with several tiered requirements, the stringency and requirements of an ecodesign Tier 2 proposal could also be subject to a review of the requirements 1-2 years before they were due to apply. This would then allow a "safety net" or feasibility check to be included, to "future proof" the Tier 2 requirements, also taking into account market developments, and the penetration of new(er) technologies.

It is recommended to organise the information on the product composition and its life cycle as in **Table 1**, which will then constitute the first step towards building the Base Case. **Table 1** represents a mapping of all intentionally and non-intentionally added substances in the product and used in its life cycle. As mentioned before, this assessment is to be performed prioritising information on substances remaining in the product, whilst being aware of substances that have been used in processing, etc., but which may not remain present in the final product per se. This information process-related is important in order to take it into account, where feasible to obtain, so that "regrettable substitution" may be avoided when proposing draft ecodesign requirements on product requirements.

[23] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52019SC0354&qid=1738751959150.

Table 1. Inventory of the relevant components, materials and intentionally and non-intentionally added substances in the product and used in its life cycle (i.e. inputs and emissions).

		Substances in the product						**Substances throughout the life cyle of the product**							
Relevant Component (cp_i)	**Material (m_i)**	Intentionally added substance function class (f1)	Intentionally added substance (name + CAS number)	Concentration in the material or relevant component (as available)	Non-intentionally added substance type*	Non-intentionally added substance (name + CAS number)	Concentration in the material or relevant component (as available)	**Life cycle process (Pi)**	Intentionally used substance function class	Intentionally used substance (name + CAS number)	Amount/ Concentration (specify if related to the relevant component, material or product)	Non-intentionally used substance type*	Non-intentionally used substance (name + CAS number)	Amount/ Concentration (specify if related to the relevant component, material or product)	**Details/ Comments/ References**
cp_1	**m_1**	f1 e.g. dye	m1f1ch1 e.g. TiO2		e.g. by-product			P1 e.g. raw material extraction	e.g. lubricating agent						e.g. input or emission
			m1f1ch2						e.g. dye						
			m1f1ch3												
		f2 e.g. hardener	m1f2ch1												
			$m1ch_n$					P2							
			...					...							
	m_2	f1	m2f1ch1												
			m2f1ch2												
			...												
	m(r)		...												
	m_n														
...															
cp_2	...		...												
...															
cp_n															
...															
final product**	n.a.							P1 e.g. assembly							
	n.a.							P2 e.g. use							
	n.a.							P3 e.g. end-of-life							

Source: JRC's own elaboration.

* Specify if break-down products, impurities, side products or contaminants during the use or end-of-life stages.

** Materials and substances for final product are only in addition to those already considered in the other rows for components and materials.

Notation used: 'cp_i': component i, 'm_i': material i, 'f_i': function of the substance, '$m_if_ich_i$': intentionally added substances, 'm(r)': recycled material; Pi (e.g., P1, P2, P3 etc): life cycle process.

Table 1 will serve to collect the intentionally and non-intentionally added substances in the product under study as well as the related life cycle processes and substances involved, i.e. the input and output amounts to each life cycle stage and each manufacturing process are suggested to be included as well. Data about the life cycle stages of the product may be used for the development of the life cycle inventory for the environmental footprint calculation (see section C1). **Table 1** is then divided in two parts.

On the left, the intentionally and non-intentionally added substances that remain in the product should be collected. The function of the substances, the concentration in the material (or in the components) should be included as well as other identification characteristics such as the hazard classification of the substances, the EC number, or other properties of interest (for simplification a column for these extra details is not indicated in **Table 1**). If a material is recycled (or it has some recycled content or recyclate in its composition, this should also be included (in **Table 1** is written as **m(r)** just to indicate the existence of recycled material).

The right side of **Table 1** serves to collect information on the intentionally and non-intentionally used or emitted substances during the life cycle of the product, where the process of the life cycle should be included adding the stage of the life of the product it belongs, i.e. extraction of raw materials, production, assembly, distribution, use or end-of-life stage, etc.

Table 1 will later be used for the building of the **Base Case(s)** depending on the scope of the product group under study which would be defined at the beginning of Task 5 of the MEErP.

It should be noted that a complete Bill of Materials (i.e. all the data contained in columns for components and materials) according to **Table 1** cannot be defined in the case of products that are **mixtures** (e.g. cosmetics, detergents, paints, lubricants, etc.), given that, for mixtures, components and materials cannot be identified; rather, solely their constituent substances can be investigated. Therefore, for products that are themselves mixtures (e.g. a paint, a lubricant), the PS team should omit the first two columns in the definition of a Bill of Materials (components and materials) and investigate the mixture composition via listing the substances that are intentionally and non-intentionally used in the mixture, together with their concentration range. Nevertheless, the PS team should still analyse the Bill of Materials of the packaging that contains the mixture, therefore collecting data on the components, materials and substances used in the packaging.

Sections below provide more details on the how to fill in **Table 1**.

In a simplified approach, only half of the left part of **Table 1**, corresponding the intentionally added substances remaining in the products, should be completed. This is illustrated in the following **Table 1 – B**.

Table 1 – B. Inventory of the relevant components, materials and intentionally added substances in the product (i.e. inputs) (simplified approach).

Substances in the product					
Component (cp_i)	**Material (m_i)**	Intentionally added substance function class (f1)	Intentionally added substance (name + CAS number)	Concentration in the material or relevant component (as available)	**Details/ Comments/ References**
cp_1	**m_1**	f1 e.g. dye	m1f1ch1 e.g. TiO_2		e.g. input
			m1f1ch2		
			m1f1ch3		
		f2 e.g. hardener	m1f2ch1		
			$m1ch_n$		
			...		
	m_2	f1	m2f1ch1		
			m2f1ch2		
			...		
	m(r)		...		
	m_n				
cp_2	...		...		
...					
cp_n					
...					
final product**	n.a.				
	n.a.				
	n.a.				

Source: JRC's own elaboration.

** Materials and substances for final product are only in addition to those already considered in the other rows for components and materials.

Notation used: 'cp_i': component i, 'm_i': material i, 'f_i': function of the substance, '$m_if_ich_i$': intentionally added substances, 'm(r)': recycled material

3.2.1 Simplified assessment for complex products

A complex product (in terms of component and material or a long and complex value chain, as is the case of smartphones) may have a high number of functions fulfilled by substances in the product and along the life cycle stages. Also, several alternative substances may be present for each function. A complex composition in terms of substances in the product and along the life cycle stages could result in highly time-consuming searches for the Preparatory Study team to complete the assessments required in Section A. Thus, depending on the complexity of the product group, a simplified assessment for building the inventory may be needed.

The proposed simplified assessment is based on a two-fold approach:

— the consideration of the functions that are more representative, i.e. the most frequently mentioned/likely to be used according to the literature sources/stakeholders;

— the consideration of the substances that are more representative, for each function i.e. those that are most frequently mentioned by the literature sources/stakeholders for each function.

With regard to the second point, in line with a **worst-case approach**, for the definition of the Base Case, the substances that are highlighted as the most hazardous from an environmental/recycling point of view (and with the greatest concentration in the Base Case) should be considered. The above considerations should take into account the relevant information for the product group available from literature, regulatory and certification schemes (e.g. relevant Best Available Techniques Reference documents (BREFs) form the Industrial Emissions Directive, negative lists from product regulations or voluntary certifications) or feedback from stakeholders received e.g. during the Preparatory Study consultations or formal consultation meetings.

If information on the share of alternative substances by mass, defined according to weighted average, are available for each function, these should be used to define the relative concentration in the Base Case, otherwise an arithmetic average can be applied.

In the same way, the definition of the average scenario (that represents current practice in companies, defined via stakeholders' data provided, LCA datasets, literature, etc.) and the best scenario (i.e. the optimised alternatives, that are not yet part of current practice, according to certifications schemes like the EU Ecolabel, etc.), may be performed, by selecting the most representative chemicals with the approach defined above. It is suggested to consider the average scenario and the best scenario when identifying the performance requirements (see section C1).

3.2.2 Product composition

Bill of Materials (components and materials of a product)

The identification of a product's components and materials should be carried out in accordance with Task 4 of the MEErP in the section dedicated to "Product weight and Bill-of-Materials". Such information is then inserted by the PS team into the **EcoReport tool**, which is used to model the impacts from the life cycle of the product under analysis[24]. As a general suggestion, no cut-off thresholds to materials are proposed.

Whenever possible, to the extent that information is available in the literature, and in the effort of anticipating steps of later tasks, it is suggested that the PS team carries out the following, to:

- Identify components and/or materials where it is market practice to use recycled materials[25]. This could contribute to later reflections on the possible presence of legacy substances[26] which could compromise further recycling of the product, e.g. presence of restricted biocides such as pentachlorophenol in recycled wood chips or paper products[27].
- Identify components and/or materials in direct contact with the consumer[28], e.g. the outer layer of a baby diaper, and those that are perfectly shielded from consumers (i.e., no risk of exposure during foreseeable use). This could be useful information to be flagged towards consumers and is potentially relevant when developing the product-specific content of the Digital Product Passport (DPP), although this is not something specifically referred to in the legal text.
- To the extent possible, identify components and materials which may be subject to potential unintended release of substances to the environment during the use stage and end of life operations[29]. This could help to identify those substances that may be subject

[24] As explained in Task B1 ('Developing a method for the assessment of life-cycle environmental impacts of products, and integration in or relation with the Methodology for the Ecodesign of Energy-related Products'), as a starting point, the LCA would be done in the EcoReport tool, also for non ErP. If there are important shortcomings, then a more comprehensive LCA is recommended. The conditions for such a choice are explained in Task B1 Report.

[25] Ardente and Mathieux, 2012. Integration of resource efficiency and waste management criteria in European product policies – Second phase Report n° 2 Application of the project's methods to three product groups (final) (JRC 77186).

[26] Legacy substances are substances that in the past were used in products, and then restricted by legislation; however, due to the long lifetime of products, such substances are still found in waste products collected for recycling, and can contaminate recycled material streams.

[27] Commission Delegated Regulation (EU) 2021/277 of 16 December 2020 amending Annex I to Regulation (EU) 2019/1021 of the European Parliament and of the Council on persistent organic pollutants as regards pentachlorophenol and its salts and esters, eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32021R0277.

[28] According to the findings of the Chemical Task Force 1 (see Annex III).

[29] According to the findings of the Chemical Task Force 1 (see Annex III).

to unintended leaching or other emissions, e.g. via dust, from the product. This could be a useful piece of information to be flagged towards consumers and end-of-life operators when developing the content of the product-specific Digital Product Passport (DPP).

In a simplified approach, the assessment of the product composition would generally focus on intentionally added substances

Intentionally added substances

Having an overview (i.e. the inventory) of substances in the product group under analysis is important for the definition of information and performance ecodesign requirements, as discussed in Sections B and C of this report.

In an ideal scenario, the PS team would list all the intentionally added substances in the relevant components, spare parts and materials of the product. However, this would be a huge task, requiring unrealistic resources on seeking data for thousands of substances, which in many instances could be proprietary data, or claimed as such, and thus not publicly accessible. Moreover, sometimes the chemical composition of the product is unknown (also to the manufacturers of the product group under analysis) especially if the supply chain is long and geographically dispersed. The variety of chemical compositions of the same product made by different companies further complicates the analysis to become very difficult. For example, feedback from industry on the number of different chemicals used in textile apparel suggests an order of magnitude of thousands of substances.

It is thus proposed that the PS team starts by listing the types, i.e. **functions** of the substances that are used in components and materials constituting the products under analysis (to the extent possible). The **functions** of the substances used in products (and components and materials) are those related to the substance composition of the materials and components themselves and to the properties provided to materials and components, such as the shape, density, durability, colour, texture, or other properties of the product (and or the component and materials). Particularly with regard to the substance composition of materials (but also applicable to substances that provide properties, the expected level of disaggregation of materials should ultimately allow the identification of substances accompanied by related CAS numbers (as requested in **Table 1**). Each CAS Registry Number (CAS RN) identifier is a unique numeric identifier that designates only one substance.

Functions should be primarily related to the use of substances for the manufacturing of the product; however, when mixtures are used in the manufacturing of the product rather than single substances, information about functions may refer to the function of substances in the mixtures. For the definition of such classes, it is proposed that the PS team refers to and uses the Technical Function categories reported in ECHA's "Guidance on Information Requirements and Chemical Safety Assessment Chapter R.12: Use description", Table R.12-15: Descriptor list for Technical functions (TF) (page 74)[30]. A non-exhaustive list of Technical Function categories applicable to the textile sector, based on the aforementioned ECHA guidance, is reported as an example in Table 2 below. The information on the function classes should be accompanied by the concentration range which is expected for that function class.

[30] European Chemicals Agency, Guidance on Information Requirements and Chemical Safety Assessment, Chapter R.12: Use description, ECHA-15-G-11-EN, ISBN 978-92-9247-685-4, December 2015, available here: R_12_CARACAL_cross_check_TC (europa.eu).

Table 2. Example from the textile sector of typical functional substances, intended to remain in the product (left column) and process (auxiliary) substances (right column). Distinction adapted from Dodd et al. (2014) and EU Ecolabel on textiles (2014/350/EU).

Substances that compose the materials and components	Substances that impart properties to the product	Process auxiliaries[31]
Synthetic polymers (such as PET)	Dyes and pigments	Carriers
Natural polymers (such as cellulose)	Optical brighteners	Levelling agents
Other natural resources (e.g. animal hair)	Plasticizers	Dispersing agents
Metals	Cross-linking agents (from easy care finishes and printing)	Surfactants
	Flame retardants	Thickeners
	Water, dirt and stain repellents	Binders
	Hardeners and softeners	pH adjusters
	Biocides	Defoamers

Source: Adapted from ECHA's "Guidance on Information Requirements and Chemical Safety Assessment Chapter R.12: Use description".

For each function it is proposed that the PS team lists relevant information on the main substances that are typically used to fulfil that function, together with the concentration ranges found in the literature. Regarding substances that impart properties to the product, to keep this task within manageable levels, it is suggested to focus on the *main substances* used to provide a specific function (see Section 3.2.1 - Simplified assessment for complex products), rather than attempting to include *all* substances. "Main substances" here would be defined as those which are the most commonly used ones under the worst-case scenario, or alternatively those for which pertinent information has been derived from more reliable sources. It is expected that main substances will be in the order of 5-10 substances per function, depending on the product group. Anyway, case-by-case considerations may still be needed according to the product specificity and the representativeness of the data obtained.

For each of these main substances identified, the PS team should also gather information on their concentration in the relevant component, material or product. It is recommended to gather such information in the form of **concentration ranges**. Such ranges will form the basis to define the Base Case(s) (see Section 3.3) and should be considered for the calculation of the inventory data for the environmental footprint of its life cycle (Task 5 of the MEErP). These "main substances" will also allow the setting of draft substance-specific considerations with respect to information requirements (and potential related exemptions) and performance requirements. This topic is also addressed in greater detail in Section B (information requirements) and Section C (performance requirements).

Once the exercise is completed, the PS team should analyse the **quality of the chemical composition data that will be used in the analysis. Annex IV** explains the recommended methodology for assessing the quality of the dataset.

In a simplified approach: NIAS do not need to be assessed in the final product

[31] Commission Decision of 5 June 2014 establishing the ecological criteria for the award of the EU Ecolabel for textile products (OJ L 174/45).

Non-intentionally-added substances

Non-intentionally added substances ("NIAS") in the final product include the unintentional carry-over of auxiliaries that have been used indirectly to give specific functions or characteristics to the product (e.g. dyeing carriers) or not (e.g. pH adjusters), as well as substances present in the product as a result of contamination (e.g. abrasion from machineries, other materials, e.g., cleaning products, etc.). "NIAS" also include impurities present in starting/ raw materials. This includes the following (see also **Figure 4**):

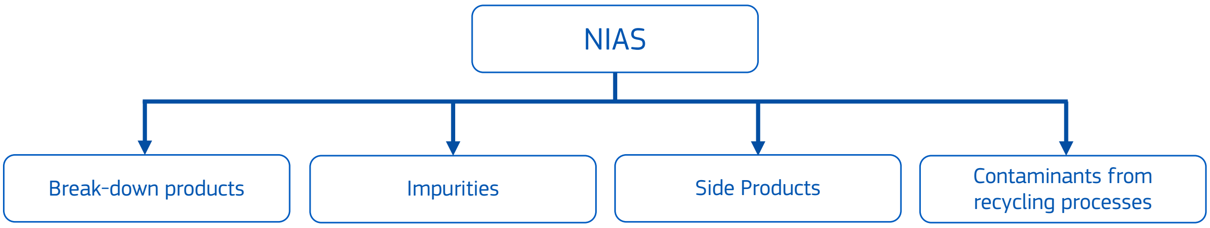
— breakdown products, resulting from the degradation of materials and chemical products (e.g. polymers and additives), that can occur during manufacturing, processing, storage or use due to e.g. heat treatment, irradiation, contact with oxygen, acids, etc.;

— impurities in the starting raw materials and unintentional carry-over of auxiliaries during manufacturing;

— side products, occurring from side-reactions besides the main chemical reaction pathways, that are possible but difficult to predict;

— contaminants from the use stage and end-of-life operations.

Figure 4. Non-intentionally added substances (NIAS) types.



Source: Adapted from Food Packaging Forum, 2013[32].

For non-intentionally added substances, it is proposed that the PS team lists the non-intentionally added substances that are typically found in the product, together with the concentration ranges that could be retrieved from the literature. As far as possible, the PS team should obtain information on the type of non-intentionally added substances that unwantedly occur in the product group under analysis, taking as a basis **Figure 4** above.

As a general rule, all substances are suggested to be investigated according to whether the data required is relatively easily available. Where the data are difficult or unfeasible to obtain, **cut-off thresholds** for mapping non-intentionally added substances in materials could be defined ad-hoc for each Preparatory Study in a way that is consistent with the approach for the identification of thresholds proposed in Section B.

Considerations on the quality and representativeness of the data collected that should be taken into account by the PS team are reported in **Annex IV**.

Substances of concern

While building the inventory of substances, there may be cases when a substance is already identified as a **substance of concern under Art. 2(27) (a), (b) or (c) of the ESPR**. If this happens, this should be flagged with a note in **Table 1** and should be further explored and confirmed when work on Section B is carried out.

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[32] Food Packaging Forum, 2013, Dossier – Non-intentionally added substances (NIAS). Prepared by Birgit Geueke. Available at: https://foodpackagingforum.org/resources/background-articles/non-intentionally-added-substances-nias.

Sources of information

In general, sources of information for the data collection process include stakeholder consultations, surveys, literature from trade associations, manufacturers, peer reviewed studies and life cycle inventories, including those used in PEFCRs (where available), or “shadow PEFCRs” (the latter being the familiar term for PEFCRs prepared in an entirely voluntary manner by the economic actors in the supply chain actors concerned).

Whenever feasible, **primary sources** of data should be preferred. However, even when primary data are available, **secondary sources** of information listed above may still be beneficial to confirm and/or complement them, for example to broaden the representativeness of the data collected and thus of the Base Case.

Overall, primary data can be obtained via exchanges with relevant stakeholders (by means of questionnaires, interviews, bi-lateral meetings, etc.)

Useful **primary sources** of data for the chemical composition of products include:

- Full material declaration (if available). It is also accessible through a specific module of the ISO/IEC 82474 1 “Material declaration Part 1: General requirement standard”[33] (now in development), if this is in place. The Material Declaration includes several declarations, i.e.:
    - Declaration for compliance. It is common practice in different supply chain that Original Equipment Manufacturers (OEMs) request suppliers to provide a compliance declaration regarding different restrictions that might impact the final product, including (but not limited to) REACH. Moreover, there are specific value chains where the suppliers also have to provide the material declaration based on the Declarable Substance List (DSL), to allow OEMs to verify the compliance (e.g. International Material Data System). These declarations specify “yes/no” and also the amounts required for a DSL according to e.g. REACH/RoHS – mandatory element;
    - Composition declaration (substance and material information) – mandatory element;
    - Process chemical declaration (process chemical substance information) – optional element that refer to composition declarations if a substance, used in a process, remains on products above a specified declarable threshold;
    - Material class declaration (material type and amount) – mandatory element;
    - Query list declarations (compliance statements for specific regulatory, e.g. “the product contains nickel that is externally accessible” and critical raw material (CRM) statements[34]) - useful points to e.g. assess the presence of chemicals in direct contact with consumers;
    - Other declarations.
- Technical documentation: these documents could provide, among others, information on the application conditions of the chemical in the product – collected for the chemicals used in the supply chain up to the material/component part supplier (as requested in general terms in the General Product Safety Regulation as regards provision of information for eliminating or mitigating risks, as regards suppliers of components, parts and software in a product);

[33] https://www.iso.org/standard/85487.html.

[34] Webinar presentation “Material Declaration according to ISO IEC 82474 1”, 14th September 2023, ISO IEC.

— Safety data sheets (SDSs) compliant with REACH Art. 31 and 32 and Annex II and with CLP Annex I requirements – collected for the chemicals used in the supply chain up to the material supplier and also GHS compliant SDS (i.e. compliant with Globally Harmonized System of Classification and Labelling of Chemicals);

— Downstream uses covered by authorisations granted (under Art. 66 REACH) for substances listed in Annex XIV of REACH (accessible via the excel file[35]);

— Information about SVHCs (SoCs Art. 2(27) (a)) as specified in Art. 33(1) and (2) of REACH which indicate that such information has to be provided to the supplier of the article and to the consumer;

— Product manual;

— Certificates/ labels, i.e. substances restricted by ISO Type I environmental labels, e.g. EU Ecolabel, Nordic Swan Ecolabel, Blue Angel – The German Ecolabel, etc.

Secondary sources of data are suggested to be considered as well, especially since primary data can be very difficult to obtain. Secondary sources of information include publications as follows:

— Literature, peer reviewed studies, company reports and LCA bills of materials;

— Best Available Techniques reference documents (BREFs), developed under the Industrial

Emissions Directive (Directive 2010/75/EU), which provide data about chemicals used in the production stages, both functional and auxiliary, emissions and resources for the conventional and lower than conventional processes, optimized processes and best available techniques for the manufacturing of products or materials (available only for certain sectors). It was assessed that the BREF for textiles seldom reports the CAS number of the substances and sometimes substance families are mentioned, rather than specific substances. Thus, where absent, the CAS numbers should be searched for in the ECHA CHEM public chemicals database[36] and other websites dealing specifically with substances (e.g. PubChem[37]);

— Declarable substance lists (DSL), such as the Global Automotive Declarable Substance List (GADSL) used by the automotive sector, or the AFIRM Restricted Substances List[38] and the Zero Discharge of Hazardous Chemicals Manufacturing Restricted Substances List[39] (ZDHC MRSL) used by the textiles and footwear sectors.

With regard to publicly available databases, the Substances of Concern present in articles as such, or in complex objects (Products) the SCIP database[40] is suggested as a valuable source of information to link the presence of substances of very high concern (SVHCs) on the Candidate List (CL) in a concentration above 0.1% weight by weight (w/w) in articles placed on the EU market. Other mandatory fields, such as the type of material in which the SVHC is present, can be also considered in defining the base case. Moreover, the database developed by the European Project Ask REACH may be a source of information for SVHCs in articles to the extent the article suppliers included such information in this database. Such database is accessible through apps like Scan4Chem, or ToxFox if directly downloaded to mobile phones and available in some MS.

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[35] https://echa.europa.eu/documents/10162/2303099/public_data_on_downstream_user_notifications_en.xlsx/4e86e561-c5c8-276b-030d-e02cbe887632?t=1674655714381.

[36] https://echa.europa.eu/fr/substance-information/.

[37] https://pubchem.ncbi.nlm.nih.gov/.

[38] https://afirm-group.com/wp-content/uploads/2024/04/2024_AFIRM_RSL_2024_0404_EN.pdf.

[39] https://mrsl.roadmaptozero.com/.

[40] Established by Art. 9 of the Waste Framework Directive (WFD). https://echa.europa.eu/scip-database.

With specific regard to the identification of the "article" category, this is done through the Combined Nomenclature (CN)[41] code and the integrated Tariff of the European Union (TARIC)[42] codes.

Information on non-intentionally added substances is challenging to obtain, given that manufacturers may not be aware of their presence. It is recommended to obtain indications on the presence of non-intentionally added substances by consulting:

— Safety Data Sheets (and extended SDS when in existence), which could also include information on possible impurities;

— Certificates and labels that indicate compliance with certain criteria on substances - usually restricting the presence of intentionally added substances, but also on possible impurities that should be avoided or maintained below certain concentration limits. Examples can include criteria on the restriction of substances in ISO type I labels (such as the EU-wide criteria for the EU Ecolabel, but also Nordic Swan, Blue Angel, and the Austrian label, …), but also other sectorial labels including criteria on substances and unwanted impurities, such as Oekotex for the textile sector[43] or the EDANA Stewardship Programme CODEX for absorbent hygiene products[44];

— Publicly available information on analytical tests from company reports as for example sustainability reports from relevant industries included in the supply chain of the BC under study;

— Confidential information obtained from relevant industries included in the supply chain of the BC under study if possible and agreed with the actors involved;

— REACH registration dossiers, if information on impurities is publicly available or obtained from relevant stakeholders.

41 https://taxation-customs.ec.europa.eu/customs-4/calculation-customs-duties/customs-tariff/combined-nomenclature_en.

42 https://taxation-customs.ec.europa.eu/customs-4/calculation-customs-duties/customs-tariff/eu-customs-tariff-taric_en.

43 https://www.oeko-tex.com/importedmedia/downloadfiles/OEKO-TEX_STANDARD_100_Standard_EN_DE.pdf.

44 https://www.edana.org/how-we-take-action/edana-stewardship-programme-for-absorbent-hygiene-products/the-edana-absorbent-hygiene-product-stewardship-programme-codex.

Definition of the Product Composition – Summary of actions to be carried out by Preparatory Study practitioners:

A summary of the methodology proposed is that the PS team should:

- follow the MEErP and identify a Base Case(s), defined as the market average product, to be used as a basis for the hotspot analysis;
- follow the MEErP and identify the product's components and materials;
- to the extent possible, identify components and/or materials where it is market practice to use recycled materials, those in direct contact with the consumer, and those which may be subject to potential release of substances to the environment during the use stage and the end-of-life operations;
- build an inventory of intentionally and non-intentionally added substances used in the product and in its life cycle (in the simplified approach, comprising only intentionally added substances used in the product);
- identify the function classes of intentionally added substances used in the product group under study, together with their concentration in the product;
- identify intentionally added substances included in the product or life cycle process, together with their concentration in the product and/or component/material. More than one substance could be identified for each function in the product/process. The selection criteria should follow the 'worst-case approach'. A simplified assessment for products with high number of substances/functions is proposed in **section 3.2.1** in relation to representativeness;
- identify non-intentionally added substances, according to their type (break-down products, impurities, side products or contaminants), together with their concentration in the product and/or component/material (not necessary in the simplified approach);
- identify input and emissions of substances, together with their amounts;
- gather concentration data on substances in the form of ranges, if available, which can be used at the moment of proposing performance requirements on substances.

3.2.3 Life cycle stages

Simplified approach: an inventory of the substances used across the life cycle of the products not necessarily compiled or assessed. However, if relevant substances in any life cycle stage are highlighted as environmental hotspots by stakeholders or via literature, these should be included in the inventory (as needed for Section C)

Task 5 of the MEErP includes an environmental hotspot analysis by means of Life Cycle Assessment modelling. This implies the research and definition, by the PS team, of the life cycle of the product under analysis, where material and energy inputs through the various life cycle stages are modelled to obtain the environmental impacts. This involves, as prescribed by the MEErP, the identification of the **main life cycle stages** that constitute the value chain of the Base Case(s) (and its sub-groups), from cradle to grave, i.e. including the extraction of raw materials, any intermediate stage (i.e. pre-processing), the manufacturing of the components, materials and the final product, the placement of the final product on the market, its use by the customer and the end-of-life stages once the product is discarded by the user. In line with the PEF methodology, the distribution stage should be included among the life cycle stages. Because of different waste management systems across the EU MSs, and the sub-optimal efficiencies of separate waste collection, the definition of the end-of-life stage will likely imply more than one treatment scenario (e.g. reuse, recycling, recovery or disposal). The PS team should also identify, for each of the life cycle stages, the **processes and sub-processes** involved.

Given the focus placed by the ESPR on substances and substances of concern, previously not the principal focus of the Ecodesign Directive, the PS team should aim to obtain an **indicative inventory of the substances used across the life cycle of the product** under analysis. With this aim, the PS team should, in order to fill in **Table 1**, and in addition to the previous steps described above:

- Identify the function classes of the substances intentionally used and/or emitted by the different processes and sub-processes of the life cycle, on the basis of ECHA's "Guidance on Information Requirements and Chemical Safety Assessment Chapter R.12: Use description", Table R.12-15: Descriptor list for technical functions.
- Creates a **list of the intentionally and non-intentionally used substances** that remain in the product, as well as **substances not remaining in the product** but rather emitted during the relevant processes used in the product's synthesis or manufacture, etc**.** The content of substances in this list should be quantified as inputs to the processes, in the form of amounts or concentration ranges (weight of substance added to the process over a reference weight[45], e.g. 1 kg or 1 unit product or component of the final Base Case), if available, and the resulting emissions that are derived from each process. Given the difficulties in identifying degraded substances which may result as emissions, the quantification of emissions should refer at least to the release to the environment of the original input substance, as a result of the mass balance[46] for each process.
- Given the difficulty in retrieving data on non-intentionally added substances, information on their concentration should be gathered to the extent feasible. Note that information should be gathered on the cross-contamination that is expected in the end-of-life stage, due to contact with other waste fractions, sorting and recycling processes. The assessment of the contamination at the end-of-life is not needed for dissipative products, i.e. products that are consumed during their service life, such as cosmetics and detergents; however, the analysis on substances on their packaging is still suggested.
- Identify the types of non-intentionally used substances, i.e. whether the substance is a break-down product, an impurity, a side-product or a contaminant (see also Section 3.2.1.3).

If already known from the steps 1-2 above, flag with a note in **Table 1** whether any of the intentionally and non-intentionally added/used substances are substances of concern under

[45] This is important in the case of processes related to the production of materials to be included in components and/or products. In such cases, it is important to report whether the weight of used substances refers to the production of a reference weight, e.g. 1 tonne, of material to be used in a component, or of a chemical product to be applied to a material, etc.

[46] The approach based on mass balance is to be interpreted as the calculation following the principle of physical conservation of mass (input minus output) and not related to the Chain of Custody model.

Art. 2(27) (a), (b) or (c) of the ESPR, to be further explored and confirmed when work on Section B is carried out.

Input amounts to each life cycle stage and each manufacturing process should also be determined as well, since these data should be used to develop the life cycle inventory for the environmental footprint calculation (see section C1).

Use phase

With respect to the use phase of products, Task 3 of the MEErP on "User behaviour" targets the understanding of behavioural trends among users in relation to the product group under study. In this Task, the PS team should identify aspects such as the way users choose to acquire the products, consumers' habits reading the product being studied during its use phase, and why/ at what point consumers decide to dispose of the products.

In the draft PS study on textiles[47], distinction could be made in relation to user behaviour aspects at pre-purchase, post-purchase and disposal stages; there might also be the need to cover product-specific aspects regarding consumer behaviour tendencies. The identified aspects will inform the modelling phase and the development of potential Ecodesign requirements. An additional analysis only partly included in the MEErP is on relevant releases from the product (e.g. leaching, migration, particulate emissions), considering the wear of the product (e.g. microfibers release from textile, particulates from tyres) and substances that may be added to the product during the use phase. Information on such use phase considerations should be included in **Table 1**. This analysis is suggested to the extent possible and depending on data availability, unless it is known that the use phase of the product triggers the use of substances that play a role in affecting its lifetime, its reliability, or EoL management (e.g. decreased durability or ease/ difficulty of recycling, etc.). In this case, the analysis should be performed.

End-of-Life scenario(s)

Depending at which type of location/ facility in the EU the product under analysis is discarded, it will face a combination of different End-of-Life treatment options, including:

- Collection systems;
- Sorting operations;
- Reuse and preparing for reuse operations;
- Recycling operations and production of recycled materials;
- Incineration and landfill operations.

Information on such End-of-Life (EoL) treatment options should be included in **Table 1**. However, note that such EoL stages are of special interest for possible contribution towards the identification of substances of concern under Art. 2(27) (d).

Collection systems

The PS team should analyse the main collection systems that are available in the EU for the product under study. This is not specifically requested under the MEErP, but it would be important regarding the following steps of researching on and identifying substances of concern under Art. 2(27) (d). In particular, the PS team should investigate whether the product is collected as part of a

[47] https://susproc.jrc.ec.europa.eu/product-bureau/sites/default/files/2024-02/Textile-Prep-Study_1st-Milestone_20240223.pdf

separate curbside collection system (as a single fraction or commingled[48] with other waste fractions), targeted by collection points, or ends up in the **mixed household waste**.

Given that the collection system may vary depending on the country or even the municipality, for the purpose of the PS it should be sufficient to gather knowledge on whether a separate collection system for the product under study (after becoming waste) exists and if such system is in place across Member States. The analysis should also cover whether an **Extended Producer Responsibility** (EPR) scheme exists, as it would affect the waste treatments following collection. Trends in the collection system for the product should be briefly discussed, together with any innovative collection systems in place in the municipalities/countries considered, but where these are not yet in an EU-wide implementation phase.

This EoL stage also includes the transportation to **transfer centres**, where usually the collected waste is gathered to be transferred to the relevant treatment option. It may be that, after the transfer centre, the collected waste is shipped to other non-EU countries for treatment or pre-treatment operations. The PS team should obtain an overview of whether shipment to non-EU countries is a general practice for the waste fraction involving the BC, including the potential mixing of different waste fractions collected from different regions. Relevant information includes the main country or countries of destination for the waste fraction, the type of treatment, and whether the waste is generally returned to the EU for further treatment, use (as recycled material) and/or disposal. Useful data on this topic can be found in the Eurostat database on Transboundary shipments of notified waste[49]. In addition, the PS team could consult the documentation accompanying the waste shipments within and beyond EU borders (i.e. the Notification and Movement Document[50], in particular regarding codes and classes and the eventual chemical analysis on the composition on waste), which could be obtained from the competent authorities.

With respect to substances, collection and transfer operations may influence and modify the chemical composition of the product under analysis via contamination. Therefore, for this stage the PS team is recommended to carry out at least a **qualitative analysis of whether chemical contamination can occur** during collection and transfer, due to e.g. mixed collection with other waste streams.

Sorting operations

Sorting operations are normally performed in order to separate waste fractions targeted for recycling. The PS team should investigate the main **sorting technologies** that can be used to sort the product waste stream from other waste fractions.

As a complementary analysis, trends in sorting technologies for the product as well as innovative technologies not yet implemented at full scale may also be identified and listed by the PS team. This information can be obtained by literature analysis. In addition, barriers to enhanced sorting efficiency should be briefly investigated.

In order to separate the target waste fractions from other unwanted fractions, sorting operations usually make use of different technologies, some of them involving the use of chemical agents, for example the use of methyl isobutyl carbinol (MIBC), diethylene glycol dibenzoate and epoxidized

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48 Commingled collection means the collection of two or more waste streams (e.g., dry recyclables) in a single container and does not impede high-quality recycling or other recovery of waste, in line with the waste hierarchy (EU Directive 2018/851). From: European Commission, Joint Research Centre, Albizzati, P., Antonopoulos, I., Caro, D. et al., Development of an EU harmonised model for separate municipal waste collection and related policy support – Literature review – May 2022, Publications Office of the European Union, 2023, https://data.europa.eu/doi/10.2760/158073

49 https://ec.europa.eu/eurostat/databrowser/view/env_wasship/default/table?lang=en&category=env.env_was.env_wasst

50 Proposal of the European Parliament and the Council on shipments of waste and amending Regulations (EU) No 1257/2013 and (EU) No 2020/1056.

linseed oil as chemical flotation agents to separate PET and PVC from post-consumer polymer wastes and virgin polymers[51].

For this task, the PS team should identify and list the main substances that are used during the sorting operations involving the product under analysis.

It should be mentioned that some automatic identification and waste sorting technologies use advanced sensor technologies to determine the chemical composition of the incoming waste. Such information allows sorting facilities to identify the presence of relevant substances that may hinder the separation of the waste, such as near infra-red spectroscopy, and can avoid cross-contamination with fractions which may make recycling processes more complex or even impossible. An example of identified substance could be brominated flame retardants in plastics from waste electrical and electronic equipment of end-of-life vehicles.

Reuse and preparing for reuse operations

"Reuse and preparing for reuse operations" refer to products that are used again for the same purpose for which they were conceived both when the product has passed through the 'waste' status ('preparing for reuse') and when not ('reuse', when the owner has not discarded the item). According to the MEErP, the PS team should identify the share of the production (quantity/volume) of the product generated as a waste that is sent to preparation for reuse (if this exists). To complement it from the point of view of substances, the PS team should investigate the main "preparing for reuse" technologies that can be used for the product, with special focus on the main reuse applications that are possible for the product group under study.

In addition to what required by the MEErP, and from the point of view of chemical substances, reuse/preparing for reuse technologies and applications should be analysed from the perspective of the substances present in the product that could end up in the reused/prepared for reuse product, given the presence of legacy substances that could impede the new (second) use of the product.

The PS team is thus recommended to **collect information** on:

- reuse / preparing for reuse technologies;
- possible second uses and applications;
- trends in the second-hand use market, including as far as possible exports to non-EU countries and private sales on web platforms;
- barriers to currently unexploited reuse applications.

Normally, reuse/preparing for reuse activities include at least a cleaning step which may use substances that may remain on the product. The PS team should thus identify and list the main substances that are used during the preparation for reuse operations (e.g. repair, refurbishing, remanufacturing, etc.) involving the product under study. If information is available, the PS team is recommended to also carry out a preliminary screening of the possible negative impacts of selected substances on the reuse/preparing for reuse technologies and applications, which could be useful for later steps proposed in this methodology to identify substances of concern hindering reuse (see Section B). This could include a brief overview of the consequences of reused products for selected applications, e.g. in terms of lifespan, maintenance, and End-of-Life treatment.

Recycling operations

Recycling is defined by the Waste Framework Directive as '*any recovery operations by which waste materials are reprocessed into products, materials or substances whether for the original or other*

[51] Mohammad Shamsaddini Negari, Saeed Ostad Movahed, Ali Ahmadpour, 2018, Separation of polyvinylchloride (PVC), polystyrene (PS) and polyethylene terephthalate (PET) granules using various chemical agents by flotation technique, Separation and Purification Technology,Volume 194, https://doi.org/10.1016/j.seppur.2017.11.062.

purposes'. Recycling operations usually include more than one step and can be based on mechanical, chemical, physical and/or thermal technologies. For a specific waste stream there can be several recycling operations available. According to the MEErP, the PS team should identify the share of the production volume of the product generated as a waste that is sent to recycling. The PS team should thus investigate the recycling technologies available in the market and relevant to the product under study. In addition to the MEErP, special attention should be given to trends in recycling activities and markets, as well as to the main applications for the recycled materials, including those applications that are promising but not yet at scale, from the perspective of substances.

The **aspects to be investigated** by the PS team, are proposed as follows:

- recycling technologies (with emphasis on intermediate processes, input/outputs, key elements such as auxiliaries needed or hotspots of the processes, closed/open loop, etc.);
- state-of-the-art and trends in the market for recycled materials;
- main recycling applications, with a qualitative overview of whether it can lead to closed-loop or open-loop recycling, and the effects on the substitution of virgin resources;
- barriers to currently unexploited recycling applications.

In addition, the PS team should identify and list the main **substances used and released** to the environment during recycling operations involving the BC, and complete **Table 1** to the extent possible. The PS team should also carry out a preliminary screening of possible negative impacts of selected substances on the recycling technologies and applications; this information could be very useful for the later steps proposed in this methodology on identifying substances of concern hindering recycling (see Section B).

The PS team should include a brief overview of the consequences of **recycled content** on selected applications, e.g. in terms of lifespan, maintenance, end-of-life treatment. As far as possible, information should be sought on substances that may end up in the recyclate and play a role for their application into new products, e.g. substances whose presence can constitute a barrier to the placing on the market of a product including recycled material (for example, manufacturers of wool garments that include recycled wool have expressed concern over the presence of the restricted group of substances, nonylphenol ethoxylates (NPEOs) wool recyclate, which therefore prevents its use in new products (for more details see Section 3.2.2.3). The above steps complement the research to be performed for the identification of SoC defined by Art. 2(27) (d) (see more details in Section B).

<u>Incineration and landfill operations</u>

Recovery (identified as R1 under the Waste Framework Directive [WFD]) and disposal (identified as D10 under the WFD) operations result in emissions such as leachates, wastewater and gaseous/particulate emissions to the atmosphere. In order to understand if relevant chemical emissions occur, it is proposed that the PS team assesses landfill/incineration scenarios relevant for the BC.

Some chemicals that are expected to be present in the final waste can be deduced from the previous mapping activity and can be attributed to the corresponding flows defined by the general post-consumer scenario rates. However, further chemicals may be produced as a consequence of the reactions happening within the disposal scenario (for example brominated dioxins and furans – PBDDs/PBDFs from the combustion of flame retardants). It is acknowledged that this task could be challenging; therefore, it is proposed to carry out the **assessment at least qualitatively**, with a view to flagging any realistically possible environmental issues stemming from the transformation of substances present in the waste, as a consequence of their final disposal. The PS team should provide an overview and evaluation of these issues. To the extent possible, the calculation of **the emissions of substances** released from the product disposal scenarios would be beneficial for the environmental footprint calculation (e.g. PFAS leaching from textiles in landfills). For the calculation of the emissions of substances, the PS team should take into account the possible “emission scenarios” or risk management measures, if they are in place.

Sources of data

Comprehensive information on the substances used in different processing steps can be obtained by consulting Best Available Techniques reference documents (BREFs), which are developed in the context of the Industrial Emissions Directive (IED) and cover many industrial activities and product sectors relevant to the ESPR (where the production is of sufficient scale to warrant coverage via the IED). However, the BREFs draw mainly on good to best techniques that are employed at full plant scale in the EU and largely represent the processing steps found in EU installations. It must be noted also that the BREFs also take into account international best practice developments, including those coming from Third Countries; the international focus of future BREFs will be further enhanced by the INCITE centre for innovation, established in the 2024 revision of the IED. Nevertheless, for many of the processes and techniques covered by the IED, and consequently the products produced via these processes, there is a risk that the techniques employed in industrial plants located outside the EU may not match those in the EU. That is, the non-EU plant may not be as up to date and, as a consequence, may have higher environmental impacts, or rely on uses of “legacy chemicals” that may be prohibited in the EU, or where there are EU policy measures in place such as REACH, RoHS, CLP or the IED itself that trigger the phase-out of such substances or chemicals.

In general, for the end-of-life stages, the most effective way to find information is probably via **interviews and/or surveys** with the actors responsible for such operations. This could be especially useful for the life cycle stages of preparing for reuse and recycling, since recycled materials are usually subject to testing and control before being placed on the market in order to comply with product-specific regulations (if any) and in line with specifications set by the next actor in the supply chain[52]. In addition, useful information could be retrieved, if available, from End-of-Waste (EoW) criteria relevant to the product upon becoming waste, from descriptions of applied recycling technologies and other relevant literature.

An example of this approach is where inputs collected from EU stakeholders indicated that the sorting operations of textile waste happening outside the EU are critical with regard to the introduction in the EU market of legacy chemicals in textiles. As an example, the presence of nonylphenol ethoxylates (NPEOs) in sorted textile material may represent a regulatory limitation for the recycling operation happening in the EU market, and in general for the circularity of the entire value chain (described in Section B2). Stakeholders report that NPEOs are still used as surfactants in detergents for washing in non-EU countries, while specific applications in textiles have been restricted in the EU since 2003, and subsequently with entries 46 and 46a of Annex XVII of REACH (Directive 2003/53/EC, Regulation 2009/552/EC, Regulation 2020/2096/EC). Stakeholders argue that during sorting, the different flows are mixed and then the sorted materials are purchased back in the EU for the following recycling process. Here the possibilities to complying with REACH restrictions on articles are reduced due to the content of the aforementioned NPEO group of chemicals, ultimately affecting the circularity of the material. More details about this feedback are provided in Section E. Considering this example, the PS team should investigate the waste flows and the conditions of the sorting process from the perspective of substances, relying on stakeholders’ experience. The CN codes may be needed to complete this mapping of waste flows.

For information on emissions of substances from incineration and landfilling of waste, ECHA guidance supporting exposure assessment in the context of a Chemical Safety Assessment, as

[52] Inputs received from stakeholders (not published).

related to environment and waste (R.16[53] and R.18[54]), can be used as a source of information. This assessment provides estimates of the release to different media from different waste management operations. In addition, peer-reviewed papers, sectoral Best Available Techniques (BAT) reference documents (BREFs) and life cycle inventories (e.g. Environmental Footprint[55] datasets, Ecoinvent[56]) can be useful sources of information for this purpose.

For information on other life cycle processes, it is recommended to rely on a targeted literature research, complemented wherever possible by stakeholder engagement.

Definition of the Life cycle stages – Summary of actions to be carried out by the PS practitioners:

A summary of the methodology proposed is that the PS team should:

- follow the MEErP and identify the typical life cycle stages of the product under analysis from cradle to grave according to the market-weighted average;
- identify the function classes of intentionally used substances in the different life cycle stages of the product group under study, and emissions to the environment along the life cycle stages, including the End-of-Life scenarios, to the extent that information is available;
- identify intentionally used substances, for the same function in the life cycle process, together with the amount or concentration used and/or amount emitted. More than one substance could be identified for each function in the product/process;
- identify non-intentionally added substances, according to their type (break-down products, impurities, side products or contaminants), together with their concentration in the product and/or component/material, and emissions to the environment along the life cycle stages, including the End-of-Life scenarios, to the extent that information is available;
- gather concentration data on substances in the form of ranges, which can be used at the moment of proposing performance requirements on substances;
- identify intentionally and non-intentionally substances that are normally used by consumers and that are likely to remain in the product once it reaches its End-of-Life;
- to the extent possible, carry out a qualitative analysis of possible cross-contamination for the collection phase at the End-of-Life stage, especially if **evidence (e.g. via stakeholders) indicates important impacts of such contamination**;
- analyse, for the End-of-life stage: trends in reuse/preparing for reuse and recycling technologies; possible second uses and recycling applications; and barriers to currently unexploited reuse and recycling applications;
- to the extent possible, identify substances that may end up in the **recyclate** and play a role

[53] Guidance on Information Requirements and Chemical Safety Assessment Chapter R.16: Environmental exposure assessment Reference: ECHA-16-G-03-EN ISBN: 978-92-9247-775-2 Publ.date: February 2016 © European Chemicals Agency, 2016.

[54] Guidance on information requirements and chemical safety assessment Chapter R.18: Exposure scenario building and environmental release estimation for the waste life stage, ECHA-2010-G-20-EN Publ.date: October 2012, European Chemicals Agency, 2012.

[55] https://eplca.jrc.ec.europa.eu/LCDN/index.html.

[56] https://ecoinvent.org/.

for their application into new products, e.g. substances whose presence can constitute a barrier to the placing on the market of a product including recycled material.

3.3 Building of the Base Case(s)

Once the **data collection process is completed**, the PS team can proceed with building the material and chemical composition of the Base Case(s) using the mapping (inventory) of substances gathered in **Table 1**. Alternatively, **Table 1 – B**, if a simplified approach is followed.

This information is normally presented at the beginning of Task 5 'Environment and Economics' of the MEErP.

The definition of the components and materials (the Bill of Materials) of the Base Case(s) should be based on the average of the data collected weighted by the market shares, according to the market data compiled in Task 2 'Market' of the MEErP.

Similarly, the definition of the chemical composition (intentionally added substances) of the Base Case(s) should be built following these steps:

1. Define, for each substance-related function class in the product, a corresponding substance concentration, by taking the highest concentration of the data collected for that function, as found in the inventory (**Table 1** or alternatively **Table 1 - B**);
2. For each function, select one specific intentionally added substance, among those identified in the inventory for that function, which can be considered **representative** of that function. For example, the substance is quoted by a number of reliable sources as being used in the product under analysis. If the reliability of the sources of information or the representativeness of the substances is not clear, the representative substance should be chosen as the one having the greatest impact, thus allowing a more precautionary approach. Whenever considered relevant and appropriate by the PS team, more than one substance can be selected for each function, following the guidelines provided in section 3.2.1 Simplified assessment for complex products;
3. For each representative substance, define its concentration in the product and at the relevant component level, by taking the highest of the data collected.

A similar approach should be followed also for non-intentionally added substances and substances used along the life-cycle, with the difference that non-intentionally added substances cannot always be assigned a function class, but only a type of non-intentionally added substance (in this report proposed as break-down products, impurities, side products or contaminants, see **Figure 4**).

This approach leads to the building of a virtual product, not actually existing on the market, and likely with a higher heterogeneity of materials and substances compared to real products on the market.

Similarly to the chemical composition of the Base Case described above, the selection and quantification of substances used over the life cycle stages of the Base Case(s) should be performed according to the following steps:

1. Define the concentration of each substance-related function class in the life cycle stage by taking the highest of the data collected for that function.
2. For each function, select one specific intentionally used substance, among those identified in the inventory for that function that can be considered **representative** of that function. For example, the substance is quoted by a number of reliable sources as being used in the product under analysis. If the reliability of the sources of information or the representativeness of the substances is not clear, the representative substance should be chosen as the one having the greatest impact, thus allowing a more precautionary approach. Whenever considered relevant and appropriate by the PS team,

more than one substance can be selected for each function, following the guidelines provided in section 3.2.1 Simplified assessment for complex products.

3. For each representative substance, define the concentration of the representative intentionally used substance in the life cycle stage by taking the highest of the data collected, if the data concern input values of substances into life-cycle processes, or the lowest of the data collected, if the data concern emission values of substances during life-cycle processes.

The information about inputs and emissions built following steps 1-3 above can then be used directly in the modelling tool that is chosen for the hotspot analysis of environmental impacts of the Base Case.

3.4 Summary of Section A

In summary, Section A provides guidance for the preliminary steps that should be carried out to develop possible information requirements on substances of concern and performance requirements on substances (see **Table 3**).

The main steps to be carried out involve the filling out of **Table 1** (see also a possible simplification in **Table 1 – B**), the inventory of the product group, which is needed to build the Base Case. This information should also be confirmed via stakeholder consultations and feed into the method for the development of information requirements (Section B) and for the development of performance requirements (Section C). In addition, the inventory of substances and subsequent Base Case should be used for the life cycle assessment and identification of environmental hotspots.

Table 3. Summary of the method in Task B5 - Section A.

Summary of the methodology in Task B5 - Section A			
Methodology step	Where?	Required by MEErP?	Any addition in Task B5?
Product composition (inventory)			
components and materials	Task 4	yes	- identify materials and components in the product - identify component and/or materials where it is market practice to use recycled materials - identify components and/or materials in direct contact with the consumer - identify components and materials which may be subject to potential unintended release of substances to the environment during the use stage
intentionally added susbtances in the product	Task 4	new (Task B5)	- identify the function of intentionally added substances used in the product - for each function, identify the main substances used to provide that function - identify the concentration range of the main substances
non-intentionally added susbtances (NIAS) in the product	Task 4	new (Task B5)	- identify main non-intentionally added substances occurring in the product - define the type* of non-intentionally added substance - identify the concentration range of the non-intentionally added substances
Product life cycle stages (inventory)			
processes and sub-processes (raw material extraction, manufacturing, use, end-of-life)	Task 4	yes	
intentionally used susbtances in all processes	Task 4	new (Task B5)	- identify the function of intentionally used substances used in the processes - for each function, identify the main substances used to provide that function - identify the concentration range of the main substances
non-intentionally used susbtances in all processes	Task 4	new (Task B5)	- identify main non-intentionally used substances - define the type* of non-intentionally used substance - identify the concentration range of the non-intentionally used substances
substances in the use phase	Task 3	new (Task B5)	- identify relevant releases of substances from the product
substances in the end-of-life	Task 4	new (Task B5)	- qualitative analysis of whether chemical contamination can occur during collection and treatment - identify the main substances that are used during the sorting operations - identify reuse/preparing for reuse technologies and applications from the perspective of the substances - identify recycling technologies and applications from the perspective of the substances
Base Case			
Definition of the Base Case	Task 5	yes	- define the concentration of each function (for intentionally added substances) or type (for NIAS) of substances in the product or used or emitted during its life cycle by taking the highest concentration of the data collected for that function - for each function, select one representative intentionally added substance - for each type of NIAS, select one representative NIAS - for each representative substance, define its concentration in the product by taking the highest of the data collected - for each representative substance, define its concentration in the life cycle stage by taking the highest of the data collected, if the data concern inputs into life-cycle processes, or the lowest of the data collected, if the data concern emissions during life-cycle processes

Source: JRC's own elaboration.

Box 2. Suggested stakeholder engagement during the steps identified in Section A of the method.

→ In the preliminary stakeholder questionnaire, information about intentionally and non-intentionally added substances included in the product and used in the life cycle is requested from stakeholders. If possible, data on substance concentration should also be sought. This should be carried out during Task 0.

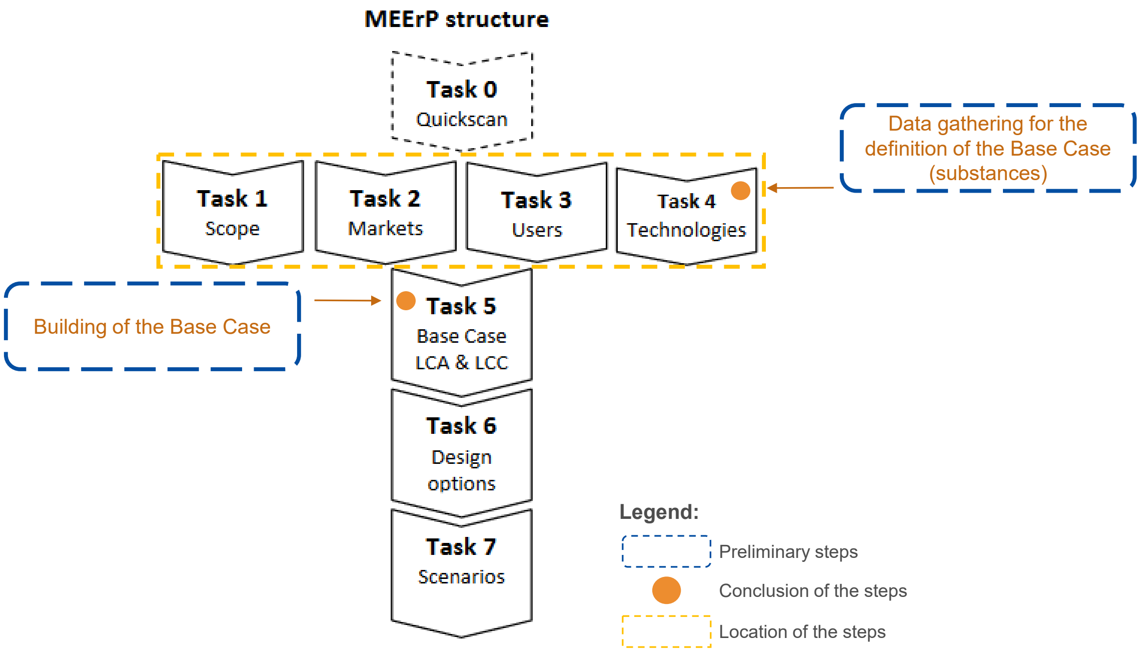
→ In stakeholder meeting number 1, where the work on Task 1 of the MEErP and preliminary work on Tasks 2-4 is discussed, the same request above should be made again to stakeholders.

→ In stakeholder meeting number 2, where the work on Tasks 2-4 of the MEErP is discussed, the PS team should present the evidence gathered about intentionally and non-intentionally added substances included in the product and used in the life cycle. Stakeholders are expected either to confirm or to provide further information on the evidence presented during and after the meeting.

→ In the last stakeholder meeting, where the work on Tasks 5-7 of the MEErP is discussed, the PS team should present the composition of the Base Case and seek input from stakeholders to confirm or to provide further information.

→ In addition, sub-groups with relevant stakeholders may be organised at any moment during the development of the Preparatory Study, as needed. Similarly, specific surveys could be developed and shared with relevant stakeholders for the request of information on substances.

Figure 5. Overview of the preliminary steps of Task B5 within the MEErP.



Source: JRC's own elaboration adapted from COWI and VHK, 2011.

4 Section B: Method for developing information requirements on substances of concern

This section aims to set information requirements on substances of concern in products, as defined under Art. 2(27) (a), (b), (c) and (d) of the ESPR, as follows:

- Section B1 addresses the identification of SoCs under Art. 2(27) (a), (b) and (c);
- Section B2 focuses on SoCs under Art. 2(27) (d);
- Section B3 discusses information requirements on SoCs under Art. 2(27) (a), (b), (c), and (d).

Section **B builds on the work carried out as explained in Section A**.

The work in Section A firstly sets the basis for identifying potential substances of concern under Art. 2(27) (d) (i.e. those that hinder reuse or recycling). Secondly, the inventory built in Section A enables the PS team to **identify which of the mapped substances in the Base Case (Section A) are SoCs as defined in Art. 2(27) (a), (b), (c) and (d)**. The aim of the derived "Bill of Substances of Concern" is to understand which substances of concern are used in the Base Case and its life cycle, and whether any of these substances may require an exemption from the mandatory information requirements proposed for each product-specific delegated act.

The suggested method in the following sections (B1 and B2) should be carried out as part of Task 5 "Environment and Economics" of the MEErP. The proposal of draft information requirements (B3) should be part of Task 6 "Design Options" of the MEErP.

4.1 B1: Method for identifying substances of concern under Article 2(27) (a), (b), and (c)

This section aims to provide guidance to the PS team as to how to identify SoCs under Article 2(27) (a), (b) and (c) in products. The starting point for this assessment is the inventory of substances in the product under analysis (**Table 1**), which led to the definition of substances in the Base Case. The PS team should then check among the Base Case substances to see which of them meet the following criteria:

- **Substances of concern defined under Article 2(27) (a)** are those that meet the criteria laid down in Article 57 of Regulation (EC) No 1907/2006 and are identified in accordance with Article 59(1) of that Regulation;
- **Substances of concern defined under Article 2(27) (b)** are those classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 in one of the following hazard classes or hazard categories: carcinogenicity categories 1 and 2, germ cell mutagenicity categories 1 and 2, reproductive toxicity categories 1 and 2, Endocrine disruption for human health categories 1 and 2, Endocrine disruption for the environment categories 1 and 2, Persistent, Mobile and Toxic or Very Persistent, Very Mobile properties, Persistent, Bioaccumulative and Toxic or Very Persistent, Very Bioaccumulative properties, respiratory sensitisation category 1, skin sensitisation category 1, chronic hazard to the aquatic environment categories 1 to 4, hazardous to the ozone layer, specific target organ toxicity – repeated exposure categories 1 and 2, specific target organ toxicity – single exposure categories 1 and 2;
- **Substances of concern defined under Article 2(27) (c)** are those regulated under Regulation (EU) 2019/1021 on persistent organic pollutants (POPs).

It is worth mentioning that SoCs under Article 2(27) (a), (b) and (c) can be unequivocally identified by their definitions above; therefore, their identification is not a core task for the PS team. Nevertheless, it is important that the PS team is aware of which substances, as relevant to the product group under study, are SoCs under Article 2(27) (a), (b) and (c), together with the possible future evolution of SoC due to, for instance, future harmonised classifications being published.

The possibility of the existence of overlaps between the three groups of SoCs (a), (b) and (c) is also noteworthy. When this happens, it is important that the substance is identified under all applicable groups. For instance, if a substance is simultaneously a SoC under Art. 2(27) (a) and (b), both categories should be reported by the PS team during the Preparatory Study.

In order to identify **SoCs under Article 2(27) (a)**, the PS team can consult the list of Substances of Very High Concern (SVHC) in the **Candidate List for REACH Authorisation** (https://echa.europa.eu/en/candidate-list-table), established according to the procedure of Article 59 of the REACH Regulation. At the moment of writing this report (last update 25 June 2025), the Candidate List contains 250 entries which include more than 490 substances, which have been identified as meeting one of the criteria a-f as referred to in Article 57 of REACH. This Candidate List is regularly updated by ECHA following agreement by the Member State Committee on the identification of the concerned substances as being of very high concern. The PS team is invited to consult the REACH Candidate List several times during the development of the PS. Prior to the formal identification and listing in the Candidate list, ECHA's website publicly informs the intention of authorities to submit SVHC identification dossiers and also about ongoing SVHC identification procedures. Forthcoming and ongoing SVHC identification cases should therefore be consulted by the PS team in the Registry of Intentions for SVHC identification, or in pages dedicated to public consultations on ECHA's website.

The identification of a substance of very high concern starts when a Member State or ECHA, at the request of the Commission, proposes a substance (full explanation in this link: https://echa.europa.eu/substances-of-very-high-concern-identification-explained) and it includes a 45-day consultation. On average, from publication of the intention, to listing in the Candidate List, for cases where there is MS agreement on SVHC identification, the process takes 10 – 12 months.

For **SoCs under Article 2(27) (b)**, the PS team should consult **Annex VI to the CLP Regulation**, which in its Table 3.1 and 3.2 lists the harmonised classification of hazardous substances for which a harmonised classification has been developed under CLP or, previously, under the Directive 67/548/EC (the Dangerous Substances Directive). Given new proposals for the harmonised classification of substances are constantly being proposed, Annex VI to the CLP Regulation is periodically updated. Consequently, the PS team is advised to consult the consolidated version of CLP Annex VI. For example, the 22nd Adaptation to Technical Progress was recently published on the Official Journal of the European Union, introducing 22 new substances with harmonised classification, modifying 16 existing entries, and deleting one.

The PS team can also obtain information on the harmonised classification and labelling of substances by consulting the Classification and Labelling Inventory managed by ECHA[57]. Current substances that would be considered SoCs under Art. 2(27) (b) number approximately 5 000, i.e., containing substances with a harmonised classification in the selected hazard classes or categories under CLP.

The harmonised classification and labelling of hazardous substances is updated through so-called "Adaptations to Technical Progress (ATP)" of the CLP Regulation which are periodically carried out by the European Commission. After the submission on an Annex VI dossier by a Member State, by ECHA at the request of the Commission or, subject to certain conditions, by a manufacturer, importer or downstream user, and the assessment and subsequent adoption of an opinion on the harmonised classification and labelling of a substance by ECHA's Committee for Risk Assessment (RAC), the European Commission, following consultation with the Expert Group for REACH and CLP (CARACAL) adopts a delegated regulation amending Annex VI to CLP. If this is not opposed during scrutiny by the Council and of the European Parliament, the act it is subsequently published as an ATP in the Official Journal of the European Union. The process, from formal submission of the

57 https://echa.europa.eu/information-on-chemicals/cl-inventory-database.

Annex VI dossier to ECHA to adoption of the ATP and publication in the OJEU can typically take approximately 2 to 2.5 years, although the time from submission of the intention to prepare a dossier, to the "register o intentions" can be longer and is very variable.

ECHA also publishes tables containing all updates to the harmonised classification and labelling of hazardous substances at the following link: https://echa.europa.eu/information-on-chemicals/annex-vi-to-clp. However, as noted in the link, "*The only official and legally-binding harmonised classification and labelling is available in Table 3 to Annex VI* to *CLP and its subsequent ATPs published in the Official Journal of the European Union. ECHA has prepared this unofficial excel table only for your convenience and ease of use*."

Finally, for full information on **SoCs under Article 2(27) (c)** the PS team can consult Annexes I to IV to the Persistent Organic Pollutants (POPs) Regulation[58].

In particular:

- Annex I substances are subject to prohibition (with specific exemptions) on manufacturing, placing on the market and use;
- Annex II substances are subject to restriction on manufacturing, placing on the market and use (currently this Annex is empty);
- Annex III substances are subject to release reduction provisions;
- Annex IV substances are subject to waste management provisions. At the time of writing this report, the Annexes contain 32 entries, although some entries cover multiple substances, thus raising the number of substances to nearly 300.

A list of POP substances can be checked in the consolidated version of this regulation, by screening Annexes I to IV the regulation. Substances listed in the POPs Regulation have previously been identified internationally as POPs, under the Stockholm Convention[59], at the proposal of a Party to the Convention and following the recommendation of the POPs Review Committee. The Preparatory Study team is advised to check the Convention's page listing "Chemicals proposed for listing under the Convention"[60] to get an indication of substances likely to be identified as POPs in the coming years, which would result in their listing also under the POPs Regulation. Although highly variable, the time from submission of a proposal for identification of substance as a POP under the Stockholm Convention and its identification as a POP by the Convention can typically require 4 – 5 years.

Also in this case, the PS team can obtain information on POPs at ECHA's dedicated webpage[61].

4.2 B2: Method for identifying substances under Article 2(27) (d)

This section proposes a method to identify substances of concern under **Article 2(27) (d)** that could be present in the final product, remain in the waste and hinder its reuse and/or recycling.

Given that this step of the method is highly dependent on the information gathered from recycling companies, companies buying recycled materials and available literature, the identification of SoCs (d) in the product will also require re-consideration of the substances previously identified in Section A. It may happen that recycling companies flag the presence of substances not previously identified

58 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32019R1021.
59 POPs listed under the Stockholm Convention: https://www.pops.int/TheConvention/ThePOPs/AllPOPs/tabid/2509/Default.aspx.
60 https://www.pops.int/TheConvention/ThePOPs/ChemicalsProposedforListing/tabid/2510/Default.aspx.
61 https://echa.europa.eu/list-of-substances-subject-to-pops-regulation.

in Section A, in which case this new information enriches the inventory of substances already built in Section A (**Table 1**).

The proposal will distinguish intentionally added substances that were used to achieve a **certain product function** from non-intentionally added substances although in the simplified approach only intentionally added substances are considered.

According to **Article 5(14) of the ESPR**, '*For each product group concerned by ecodesign requirements, the Commission shall determine, where relevant, which substances fall under the definition in Article 2(27), point (d), taking into account, at least, whether:*

> *(a) based on standard technologies, the substances make the reuse, or recycling process more complicated, costly, environmentally impactful, or energy- or resource-demanding;*
>
> *(b) the substances impair the technical properties or functionalities, the usefulness or the value of the recycled material coming from the product or products manufactured from that recycled material;*
>
> *(c) the substances negatively impact aesthetic or olfactory properties of the recycled material*'.

In order to identify SoCs under Art. 2(27) (d), it is proposed that the PS team assesses both of the following:

- Existing **regulatory limitations**[62] to the placing on the market or use of substances (in force or in preparation); as well as **customer**[63]**-driven limitations** along the supply chain. This screening is also relevant for identifying substances in the product that could be identified as SoCs under criteria (a), (b) and (c) of Article 2(27).
- **Technical constraints**, interfering with the processes leading to reuse, preparing for reuse or recycling, or with the functionality, usefulness, value and aesthetics of the resulting recycled materials or products for reuse (as specified in Article 5(14)).

Moreover, it is suggested that SoCs under Art. 2(27) (d), as identified in Preparatory Studies for other products, or specifically addressed in previous ESPR delegated acts, should be screened and taken into consideration as well, should the characteristics of the products be similar.

Existing regulatory and customer-driven limitations

The identification of substances that may hinder reuse and/or recycling should start by mapping relevant substances for which there are already existing regulatory or customer / supply-chain driven limitations, in the form of maximum concentration thresholds, applicable to the products concerned or to the materials they contain. If such limitations are already in place, the concerned substances should not be present above the allowed concentration limit in new products placed on the market (in the EU). However, the substances in question may still appear in concentrations higher than the newly applicable concentration threshold in products that were placed on the EU market in the past, before limitations were in place (especially if the product concerned is characterised by a long lifetime). In such cases, restricted substances may appear as legacy substances in products prepared for reuse or in recyclates, thus presenting a risk of hindering the circularity of the reused products or the secondary materials in new products.

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[62] This type of limitation is in line with the study carried out by Ökopol GmbH, sofia and RPA in 2020 (as summarised in Annex III), that investigated information flows on substances of concern (but defined differently compared to ESPR) in products from supply chains to waste operators

[63] Customer is intended here as the entity purchasing reused or recycled materials (recyclates).

The identification of such substances by the PS team, is made possible thanks to the **“worst-case approach” adopted in Section A**, which is relevant to the identification of SoCs that hinder reuse and recycling.

Recycled materials included in the components and products should be mapped as shown in Table 1, Section A. Table 1 is also relevant for identifying possible legacy substances. It is acknowledged that the longer the typical service life of a product is, or a component of that product, the greater is the challenge to identify the possible legacy substances present. Sources of information for these are already set in Section A.

Other substances, not meeting these criteria but restricted for safety reasons under relevant product legislation, could be proposed as candidates to be identified as SoCs (d) – and to be flagged in the DPP.

Regulatory limitations to reuse or recycling

Potential limitations to reuse or recycling may arise at the interface between product and waste legislation, as recycled or reused products may not be able to comply with existing requirements applicable to products placed on the market, as explained in the following paragraphs.

With regard to **product legislation**, potential limitations include restrictions on substances due to safety concerns, although evidently such limitations are important in order to clean material cycles from hazardous substances. This was already highlighted by Ökopol GmbH, sofia and RPA, who acknowledged the possible presence of what the study defined in 2020 as “*hazardous SoCs”* (Ökopol GmbH, sofia and RPA, 2020).

Often, substance limitations, as for example in the Toy Safety Directive or the Cosmetic Products Regulation or in the case of most REACH restrictions, with some exceptions, apply to products placed on the market, independently of whether they contain recycled or virgin materials.

Exceptions include certain restrictions in EU legislation (for example specific REACH and POP restrictions) that proposed a specific approach towards the presence of certain substances in recycled materials, as opposed to virgin materials, as stated in the Chemicals Strategy for Sustainability:

“*As a principle, the same limit value for hazardous substances should apply for virgin and recycled material. However, there may be exceptional circumstances where a derogation to this principle may be necessary. This would be under the condition that the use of the recycled material is limited to clearly defined applications where there is no negative impact on consumer health and the environment, and where the use of recycled material compared to virgin material is justified on the basis of a case by case analysis*”[64]

A practical example of this approach is the restriction under REACH on nonylphenol ethoxylates (NPEOs or NPEs), which is listed and described below. To assess the relevance of such regulatory limitations, if any, for the product group under study, it is suggested that the PS team consults existing and upcoming restrictions in Union product legislation, focusing on those restrictions that affect the product group under examination. Examples where chemical safety-based restrictions on substances may also compromise the circularity of recycled materials include:

- REACH restrictions on cadmium[65] and lead stabilisers[66] in PVC;

[64] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, Chemicals Strategy for Sustainability, COM(2020) 667 final, 2020

[65] ANNEX XVII TO REACH – Entry 23

[66] Commission Regulation (EU) 2023/923 of 3 May 2023 amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council as regards lead and its compounds in PVC (OJ L 123/1)

- REACH restriction on nonylphenol ethoxylates[67] in textile articles, expected to be washed in water, where a derogation to the restriction is envisaged for "*new textile articles produced, without the use of NPE, exclusively from recycled textiles*". (for more details see the example about the input received from stakeholders (not published) in paragraph "Sorting operations" in Section A and Annex VI);
- The presence of HBCDD (hexabromocyclododecane) in recycled polystyrene (derived largely from waste Expanded Polystyrene (EPS)and Extruded Polystyrene (XPS) from demolition) for which revised UTC (Unintentional Trace Contaminants) limits[68] have been recently set in Annex I to Regulation (EU) 2019/1021 (the POPs Regulation);
- The presence of restricted PBDEs (polybrominated diphenyl ethers) in plastics (including recyclates) or in articles, for which a sum limit of 500 mg/kg applies (Unintentional Trace Contaminant limit specified in Annex I to the POPs Regulation). Concerns have been expressed by some stakeholders[69, 70] as regards the feasibility of meeting this limit and, particularly, of lower limits, already adopted for waste, and which at the time of writing this document are under discussion towards lowered UTC limit values.
- Concerns have been also expressed by the textile industry about the possibility to comply with the limits in the proposal for restriction of per- and polyfluoroalkyl substances (PFAS)[71] for the textile sector, mainly because of the inability to correlate the fluorine detected analytically with concentrations of PFASs. (Global textile based on Ecotextile, 2023[72])

In addition, the PS team **is advised** to take into account substances that are under consideration for identification as SVHC under REACH. As mentioned in Section B1, the list of SoCs under Art. 2(27) is dynamic, since the Candidate List for REACH authorization is regularly updated when more substances are identified as SVHC. The SVHC identification process takes time, and interested parties can get advance notice of substances intended to be proposed as SVHCs for Candidate List inclusion via the Registry of Intentions[73] (RoI) as well as the Public Activities Coordination Tool[74] (PACT) on ECHA's website. The PACT and the RoI facilitate a timely preparation for companies in identifying substances that are under authorities' scrutiny and might be included in the Candidate List in the future. These substances, if relevant for the product under study, could be flagged in the Preparatory Study due to a potential future regulatory limitation if identified as SVHC and therefore, possible future identification as SoC (a) and (d).

With regard to **waste legislation**, limitations may exist in relation to waste treatment or to the conditions imposed on waste in order to cease the "waste" status (i.e. End-of-Waste criteria), as set in Article 6 of the Waste Framework Directive. Knowledge concerning the presence of certain substances in the waste may be very relevant for waste operators and recyclers, in order to take

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67 ANNEX XVII TO REACH – Entry 46a, https://echa.europa.eu/documents/10162/7dcd73a4-e80d-47c5-ba0a-a5f4361bf4b1

68 Regulation (EU) 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants, https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32019R1021&qid=1717757892228.

69 EuRIC position paper. https://euric-aisbl.eu/resource-hub/press-releases-statements/eu-pops-regulation-joint-statement-on-the-proposed-utc-value-for-pbdes.

70 FEAD position paper. https://fead.be/wp-content/uploads/2024/02/Joint-Statement-on-the-Proposed-UTC-Value-for-PBDEs.pdf.

71 ECHA, ANNEX XV RESTRICTION REPORT PROPOSAL FOR A RESTRICTION SUBSTANCE NAME(S): Per- and polyfluoroalkyl substances (PFASs), 2023, https://echa.europa.eu/documents/10162/1c480180-ece9-1bdd-1eb8-0f3f8e7c0c49.

72 Research demonstrates PFAS levels in recycled textiles - Global Textile Source, https://globaltextilesource.com/news/research-demonstrates-pfas-levels-in-recycled-textiles.

73 http://echa.europa.eu/web/guest/addressing-chemicals-of-concern/registry-of-intentions

74 http://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern/pact.

informed decisions on waste management operations (Ökopol GmbH, sofia and RPA, 2020). Where End-of-Waste criteria are defined for a material, exceeding limit values for substances will generally impede the material ceasing to be waste and thereby preventing it from being included into a new product.

The PS team is thus recommended to consult **End-of-Waste criteria** developed for relevant waste fractions, where they exist. Examples of existing End-of-Waste criteria at EU and national level comprise:

- Section 1 "Quality of glass cullet resulting from the recovery operation" to Annex I to Regulation (EU) No 1179/2012 establishing criteria determining when glass cullet ceases to be waste under Directive 2008/98/EC, requires the material not to exceed the concentration limits laid down in Annex IV to Regulation (EC) No 850/2004/EC[75];
- Criteria 1 "Quality of scrap resulting from the recovery operation" to Annex I to Regulation (EU) No 333/2011[76] requires that the total amount of foreign materials (steriles, such as non-ferrous metals) shall be below or equal to 2 % by weight;
- Annex I to the Italian Decree[77] setting End-of-Waste criteria for vulcanised rubber originating from end-of-life tyres sets a sum limit value of 20 mg/kg for the sum of 8 polycyclic aromatic hydrocarbons. This limit is consistent with that proposed, for the same PAHs in granules and mulches under the restriction 50 (9) and 50(10) in Annex XVII to the REACH Regulation;
- End-of-Waste criteria are currently being developed by the European Commission for textiles and plastics materials.

Customer-driven limitations

Specific requirements from industry practice may address the presence of certain substances in products, which may not be met by reused and recycled materials. These limitations or pressures are exerted by **actors in the supply chain**, sometimes on behalf of the final consumer, on the waste chain actors or on the suppliers of the raw materials.

These customer-driven requirements may be more stringent compared to those stemming from regulatory obligations (as reported in bilateral exchanges with stakeholders on NPEOs in textiles – not publicly available). In general, these customer-driven pressures/minimum requirements may take the form of **voluntary "negative lists" that identify** specific unwanted substances, as well as certification schemes including specific criteria on the presence of substances. Examples of voluntary negative lists are the ZDHC (Zero Discharge of Hazardous Chemicals) Gateway for textiles[78] and the Manufacturing Restricted Substance Lists (MRSLs)[79]. Examples of certification schemes include the Global Recycled Standard (GRS)[80], the OekoTex standard for the textile sector or the Global Automotive Declarable Substance List (GADSL)[81] for the automotive sector.

With respect to certification schemes, among the different types that are available in the market, a special case comprises those which are classified as "Type I" certification/ labelling schemes,

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75 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32019R1021&qid=1717757892228.

76 COUNCIL REGULATION (EU) No 333/2011 of 31 March 2011 establishing criteria determining when certain types of scrap metal cease to be waste under Directive 2008/98/EC of the European Parliament and of the Council (OJ L 94/2).

77 DECRETO 31 marzo 2020, n. 78. Regolamento recante disciplina della cessazione della qualifica di rifiuto della gomma vulcanizzata derivante da pneumatici fuori uso, ai sensi dell'articolo 184 -ter del decreto legislativo 3 aprile 2006, n. 152. https://www.gazzettaufficiale.it/eli/id/2020/07/21/20G00094/sg.

78 https://www.zdhc-gateway.com/.

79 http://www.roadmaptozero.com/.

80 https://textileexchange.org/knowledge-center/documents/global-recycled-standard-grs/

81 https://www.gadsl.org/.

according to ISO standard 14024 on environmental labelling programmes. Type I environmental certifications and labels, by definition, must cover the whole life cycle of the product, and are developed through a transparent and multi-stakeholder participatory process, and are third-party verified. Examples of ISO type I environmental labels include the EU-managed EU Ecolabel[82], the Scandinavian Nordic Swan, and the German Blue Angel.

Despite not being set in regulatory limits, product manufacturers may require their suppliers to comply with such lists or certification schemes, for instance via technical agreements (e.g., in a Business-to-Business contract). One example is the Global Automotive Declarable Substance List (GADSL), which is aligned with different international safety-based pieces of legislation which impact the automotive value chain globally. The GADSL comprises information and restriction requirements; however, these considerations might also be extended to other types of lists. In the case of GADSL, listed substances are *de facto* subject to information requirements (e.g. requested to be declared if present above a specific concentration on material weight through the MDS - Material Data Sheet) and some substances are also subjected to restriction requirements. The GADSL, by requiring the fulfilment of the most stringent limits adopted within its scope, ensures that materials and components placed on the global marked are compliant internationally in all relevant countries applying such safety-based legislation. The corollary is that, for any country requiring less stringent limits, the GADSL might represent a value chain limitation.

Supply chains and their actors may also decide to set stricter, more ambitious aims, and also include substances that are not restricted in such lists as the GADSL. For illustration, this might include a group of substances that belong to the same family of substances that are restricted, in line with the precautionary principle, formulated in this manner in order to anticipate potential legislation and/or to improve the environmental performance of their products. Such an example of a list with higher ambitions is the "Substitute It Now (SIN) List", published by ChemSec[83]. The SIN List provides a list of substances which, according to the publishing organisation, meet the criteria for identification as SVHC and, accordingly, their substitution should be prioritised. Another example could be the case of supply chain restrictions on substances in textiles classified as carcinogenic, mutagenic and toxic to reproduction (CMRs) before the entry in force of the related REACH restriction (entry 72 of Annex XVII).

In light of the above, the PS team is recommended to assess the relevance of customer-driven limitations, if any, for the product group under study. For this, it is recommended to consult **sector-specific lists**, as well as certification schemes and standards.

It is worth noting that a substance meeting the criteria of SoCs (a), (b) or (c) could also qualify as SoC (d) (for regulatory and customer-driven limitations and technical constraints). In such cases, the PS team is advised to associate to the substance all the relevant SoCs categories.

Technical constraints

Technical constraints refer in this context to the aspects listed in **Art. 5(14)** of the ESPR. In addition, the Communication on the implementation of the circular economy package: options to address the interface between chemical, product and waste legislation[84], issued in January 2018, also stated that:

- "Recycling and reuse can be hampered by the presence of certain chemicals. Some chemicals can simply constitute technical barriers preventing recycling. Even a benign

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82 https://environment.ec.europa.eu/topics/circular-economy/eu-ecolabel_en.

83 https://sinlist.chemsec.org/.

84 COM(2018) 32 final. Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on the implementation of the circular economy package: options to address the interface between chemical, product and waste legislation. https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:52018DC0032.

substance, which for example has a strong smell, could in some cases prevent use of the recycled material. Other chemicals are hazardous to humans or the environment. A growing number of these are being identified and becoming subject to restrictions or prohibitions. These chemicals may be present in products sold before the restrictions applied, some of which have a long lifetime, and therefore prohibited chemicals can sometimes be found in recycling streams. Such substances can be costly to detect or remove, creating obstacles in particular for small recyclers. All these different types of chemicals we call 'substances of concern' in this Communication."

- These technical constraints can be further clustered as process-disturbing and quality-disturbing SoC, according to the terminology used in Ökopol GmbH, sofia and RPA (2020), and as explained below.

Process-disturbing SoCs, are substances that can disrupt the waste treatment process[85] making the reuse, or recycling process more complicated, costly, environmentally impactful, or energy- or resource-demanding. For example, the use of carbon black as a pigment in plastics can result in severe interference with the identification and separation of plastics by polymer type when using near-infrared based automatic plastic waste sorting, due to the fact that the carbon black absorbs most of the radiation, thereby making the analysis of the reflected spectrum very difficult or impossible.

It should be noted that a substance added to or present in a product can hinder one recycling process but may not interfere with other possible recycling processes for that same product/material (e.g. thermo-chemical recycling of man-made fibres is more tolerant to contaminants, compared to thermo-mechanical or chemical recycling technologies and does not require decontamination of the input textiles[86]).

It is proposed that the PS team focuses on those process-disturbing SoCs mainly related to the current technology. The PS team should also expand the analysis, where feasible, to other potentially applicable, already on the market and emerging recycling options. Following this approach, the PS team should study alternative configurations (compared to when SoCs (d) are present) regarding the following aspects:

- Substances and mixtures that would not be added or used in the recycling process if the process-disturbing substance were not present;
- Increased pre-treatments or energy consumption that would not be needed if the process-disturbing substance were not present;
- Addition of workplace management measures to contain airborne emissions that would not be needed if the process-disturbing substance were not present;
- Addition of waste or wastewater treatment / management measures that would not be needed if the process-disturbing substance was not present;
- Reduced capacity (e.g. ton/hour) and efficiency (e.g. secondary material over the input waste) of the treatment process;
- Relative damage to the treatment equipment (e.g. corrosion) where the process-disturbing substance is firstly present, and secondly absent.

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[85] Aligned with point 9a of *Draft agreement on the identification of SoC (c) from co-legislators*.

[86] Duhoux, T., Maes, E., Hirschnitz-Garbers, M., Peeters, K., et al., Vito, CENTEXBEL, EcoLogic, Study on the technical, regulatory, economic and environmental effectiveness of textile fibres recycling, Final Report, November – 2021, doi: 10.2873/828412.

Quality-disturbing SoCs[87], are substances that reduce the (technical) quality and performance characteristics of the recyclate (e.g. copper in steel[88]). These include substances that alter the mechanical, technical, chemical and physical properties of the recyclate, preventing it from achieving the desired/expected performance and therefore being taken up by the market or being able to compete with virgin alternatives.

The loss of performance can be due to the presence of certain chemicals (e.g. label adhesives which confer a grey colour to recycled plastics[89]) or to the effect of the recycling process itself on chemical constituents (e.g. thermal degradation of polymers). This loss of performance can have two main consequences: firstly, it may limit the market uptake of the recyclate and, secondly, it may limit the number of possible applications for the recyclate, i.e. the number of products in which the recyclate could be used.

The situation should also be considered where a substance negatively affecting one type of application for the recyclate may not hinder *other* possible applications. For example, greyish recycled plastic pellets cannot be used for making transparent bottles due to aesthetic (or even functionality) reasons, but mayn be used for making plastic benches. However, the market value of greyish (discoloured) recycled pellets will differ from those with no discolouration, as well as the lifetime and environmental impacts of the product in which the recyclate is used.

The Staff Working Document[90] accompanying the "Communication on the implementation of the circular economy package: options to address the interface between chemical, product and waste legislation", already referred to above, provides an example of a possible quality-disturbing substance in its footnote 19, which reads "*substances which pose technical problems for recovery operations, even if not specifically flagged from the toxicological point of view, could also be considered. Eurometaux reports in its contribution to the targeted stakeholder consultation that presence of bismuth is problematic for the recycling of copper, given it is very difficult to separate both metals*".

An example of the above is where the use of bismuth in certain copper alloys, although it confers specific properties to the product, creates severe obstacles to the separation of high-purity copper, suitable for instance for drawing copper wire. The underlying reason for this is that bismuth produces grain boundary embrittlement in copper, affecting the processing of the material, especially in hot-working and forming processes. This example touches on the two types of technical constraints mentioned above:

- process-disturbing, due to the difficulty in the metallurgical separation of high-grade copper); and
- quality-disturbing, given that any remaining presence of bismuth in recovered copper affects its performance in the recycling application.

For this, it is proposed that the PS team studies the following aspects:

- Reduced lifetime (e.g. hours, years, cycles) of the recycled material due to the presence of the quality-disturbing substances;
- Mechanical, physical, chemical, and other technical properties (e.g. hardness, stress resistance, resilience, impact resistance, elasticity, plasticity, workability, ductility,

[87] Aligned with point 9b of Draft agreement on the identification of SoC (d) from co-legislators.

[88] Daehn, K. E., Cabrera Serrenho, A., Allwood, J. M., How Will Copper Contamination Constrain Future Global Steel Recycling?, Environmental Science & Technology, 2017, doi: 10.1021/acs.est.7b0099.

[89] https://www.oecd.org/chemicalsafety/risk-management/sustainable-plastic-products-detergent-bottles.pdf.

[90] SWD(2018) 20 final. https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=SWD:2018:20:FIN.

malleability, etc.) that are or may be impaired due to the presence of the quality-disturbing substances;

- Addition of virgin materials or chemical substances that would not be needed if the quality-disturbing substance were not present;
- Negative aesthetic impacts (e.g. colour, surface pattern, opacity and transparency, touch responses) or olfactory properties of the recycled material, due to the presence of the quality-disturbing substance, that lead to a negative impact on comfort felt by consumer (for applications that are in direct contact with the consumer).

In order to readily identify process-disturbing and quality-disturbing SoCs, it is suggested to carry out both a **stakeholder consultation and literature analysis,** as the starting points to identify the most frequent SoCs in products and in the associated waste and resulting recyclate.

Given that the analytical determination of substances in materials and products may be very resource-demanding and yield only limited results (since it may be difficult to replicate the large and heterogeneous conditions of a sorting/recycling process), it is proposed that the identification of SoCs under Article 2(27) d should rely primarily on a literature review (e.g. peer reviewed studies, BREF documents, websites of recycling companies) and survey/interviews with stakeholders. The emphasis should be placed on obtaining evidence from sorting and recycling companies that receive the input waste stream associated with the product group under analysis. Recyclers are often the best placed actors in the value chain to report which substances create problems when producing a secondary material, for which there is a demand in the market, given they are ultimately responsible for this placing on the market.

In addition, surveys should also address (potential) buyers/users of secondary materials, as they are likely to be aware, via their internal quality control procedures, of which substances are present in recyclates and whether they pose problems towards the intended uses. Among possible sources of data, European-wide associations of waste managers such as EuRIC[91] and FEAD[92] may be able to provide specific and cross-sectoral expertise on a broad range of materials.

The PS team should also try to obtain data regarding the **concentration** at which the identified SoCs under Art. 2(27) (d) actually impede preparation for reuse or recycling, because it could lower the quality of the recyclates. This concentration, hereafter referred to as the **alert concentration** (c_{alert}) for technical constraints is intended as the concentration indicated by recycling companies that would lead to disposing of the waste via incineration or landfill, and where it is not feasible to manage and reduce the concentration of the SoC via pre-treatments prior to the recycling processes located "downstream". This concentration is proposed to be used as the concentration in the Base Case, according to the worst-case approach. Where information is available, the alert concentration can also be expressed as the concentration of the substance at which its presence would prevent the material from being treated via specific recycling technologies.

However, as previously mentioned, it is important to bear in mind that a substance which is problematic for recycling process A may not cause any issues with regard to recycling process B (e.g.: plastics for food packaging vs plastics for garden benches).

This is where the analysis of different possible recycling processes and secondary applications suggested in Section A comes into play. At this stage of the methodology, it is suggested to list as candidate for SoCs (d) all substances that have been identified to be problematic with regard to at least one recycling process/technology/application. Further analysis and engagement with stakeholders will help the PS team to decide which of these substances should be retained as SoCs under Art. 2(27)(d). Depending on data availability, the alert concentration may be referred to with

91 https://euric.org/.
92 https://fead.be/.

respect to the material, component or the final product. Any information on possible additional effects due to the combination between different types of substances identified as potential SoCs should also be taken into consideration, for example due to incompatibilities among substances, or where additivity effects might occur under specific conditions. This may not be easily obtainable or readily known information, given the novelty of the concept of substance of concern due to circularity reasons rather than in the more established terms of its chemical safety *per se*.

Table 4 provides a non-exhaustive list of substances which, based on the broad narrative criteria defined in Article 5(14), could qualify as substances that hinder recycling and/or reuse due to technical constraints associated with their effect on waste treatment processes or on the quality, performance and use of the resulting recyclate, or when prepared for reuse of products.

Table 4. Examples of substances possibly hindering reuse and recycling of materials.

Product group	Substance	CAS	Substance family	Origin/function	Materials	Intentionally and non-intentionally added substances (NIAS)	Life-cycle stage of the final product in which it is used	Description of the technical constraints (process and quality disturbing)	Source
Textiles	Cyclic trimers of PET .e.g. Ethylene Terephthalate Cyclic Trimer	7441-32-9	Trimers	Raw materials of PET	PET, recycled PET, acrylic	NIAS	They arise on the polymer surface during textile dyeing	Quality/process disturbing: “Major problems associated with oligomer deposits in textile processing are: visual problems (cloudy appearance) at dark shades and lower brilliancy of shade due to deposition the surface of the fibre; efficiency decrease and more frequent cleaning of the dyeing apparatus due to precipitation on the dyeing apparatus; deposits on the guide rollers of the yarn winding apparatus; dusting on air-jet looms; and more frequent cleaning of production units” (1) “These oligomers can adversely affect the processing of recycled PET, such as dye precipitation on fabric and increased yarn friction.” (2)	(1) Eren and Anis, 2009[93] (2) Bingnan et al., 2023[94]
Textiles	/	/	Volatile organic compounds	Degradation product of PET due to wear and recycling	recycled PET	NIAS		Process disturbing for thermo-mechanical recycling: “These can diffuse through the melt and hinder processing, reduce output properties, or even corrode processing equipment”	Duhoux et al., 2021[95]

93 Eren, H. K. and Anis, P., Surface Trimer Removal of Polyester Fibers by Ozone Treatment, Textile Research Journal Vol 79(7): 652–656 DOI: 10.1177/0040517508097521 https://journals.sagepub.com/doi/epdf/10.1177/0040517508097521.

94 Bingnan Mu, Yuanyi Shao, Lauren McBride, Hannah Hidalgo, Yiqi Yang, Rapid fiber-to-fiber recycling of poly (ethylene terephthalate) and its dye from waste textiles without damaging their chemical structures, Resources, Conservation and Recycling,Volume 197,2023,107102,ISSN 0921-3449,https://doi.org/10.

95 Tom Duhoux, Edwin Maes, Martin Hirschnitz-Garbers, Karolien Peeters, Lise Asscherickx, Maarten Christis, Birgit Stubbe, Philippe Colignon, Mandy Hinzmann, Anurodh Sachdeva, Study on the technical, regulatory, economic and environmental effectiveness of textile fibres recycling, Final report, 2021, 10.2873/828412.

Product group	Substance	CAS	Substance family	Origin/function	Materials	Intentionally and non-intentionally added substances (NIAS)	Life-cycle stage of the final product in which it is used	Description of the technical constraints (process and quality disturbing)	Source
Textiles	/	/	Chlorinated substances	Anti-felt treatment of wool - oxidative treatment	Cashmere, wool	Functional chemical	Finishing	Quality disturbing: "The treatment process of wool fibers by chlorinated materials has resulted in noticeable yellowing and darkening of the wool, which is due to the formation of lanthionine and lysinoalanine resulting from a severe alkaline reaction of sodium hypochlorite with disulfide bonds of the cystine amino acid."	Boostani et al., 2024[96]
Textiles	Hydrogen peroxide	7722-84-1	Peroxides	Bleaching - oxidative treatment	Cashmere, wool, cotton	auxiliary - not in the final product	Bleaching (dyeing pre-treatment)	Quality disturbing: "The uncontrolled decomposition of hydrogen peroxide gives rise to OH* radicals. These radicals attack the cellulose fibre starting with oxidation of the hydroxyl groups and eventually ending with the cleavage of the cellulose molecules, decreasing the degree of polymerisation. [...] In order to inhibit these reactions, bleach stabilisers, containing sequestering agents, are usually applied."	BREF textile, 2023[97]
Textiles	Polyurethane	9009-54-5	Polymers	Used as raw material to produce elastane, it increases the flexibility and comfort	Elastane (also known as Lycra® or spandex)	Functional chemical	Manufacturing	Process disturbing: "With the exception of thermochemical recycling, elastane acts as a contaminant in all textile fibres recycling technologies, impacting the (economical) feasibility and environmental cost of the recycling process. For most mechanical recycling technologies, a presence of more than 10% of elastane can be problematic as these are more difficult to shred or unravel."	Duhoux et al., 2021[98]

96 Boostani, B., Bidoki, S.M. & Fattahi, S. Green, Eco-Friendly, and Waterless Anti-Felting Process by Three Different DESs, Compared with Chlorinated Anti-Felting Process to Produce Superwash Woolen Goods. Fibers Polym 25, 131–144 (2024). https://doi.org/10.1007/s12221-023-00411-5.

97 Joze Roth, Benoit Zerger, Damien De Geeter, Jorge Gómez Benavides, Serge Roudier, Best Available Techniques (BAT) Reference Document for the Textiles Industry, Publications Office of the European Union, Luxembourg, 2023, doi:10.2760/355887, JRC 131874.

98 Tom Duhoux, Edwin Maes, Martin Hirschnitz-Garbers, Karolien Peeters, Lise Asscherickx, Maarten Christis, Birgit Stubbe, Philippe Colignon, Mandy Hinzmann, Anurodh Sachdeva , Study on the technical, regulatory, economic and environmental effectiveness of textile fibres recycling, Final report, 2021, 10.2873/828412.

Product group	Substance	CAS	Substance family	Origin/function	Materials	Intentionally and non-intentionally added substances (NIAS)	Life-cycle stage of the final product in which it is used	Description of the technical constraints (process and quality disturbing)	Source
				of textile products				Moreover, this fibre is "invisible" to the near-infrared (NIR) technology.	
Metals	Copper	7440-50-8	Heavy metals	Post-consumer waste steel	Steel	NIAS	EoL, originating mostly from copper wires and motors in automobiles, appliances, and machinery that attach to steel during shredding.	Quality disturbing: "Concentrations of copper over 0.1 wt % cause hot shortness, a phenomenon leading to surface cracking in hot rolling and forming" Quality disturbing: affects slightly the loss of strength during wire drawing of steel	Daehn et al., 2017[99].
Metals	Bismuth	7440-69-9	Heavy metals	Substitute of lead to improve the machinability of copper alloys	Copper	Functional chemical	Metallurgical manufacturing process	Process disturbing: "Bismuth produces grain boundary embrittlement in copper, affecting the processing of the material, especially in hot-working and forming processes"; Quality disturbing: "Due to its physical properties (it expands when solidifying), bismuth tends to create mechanical stress which, in turn, causes stress corrosion cracking in components."	Duscher et al., 2004[100] Deutsches Kupferinstitute [101]

[99] Daehn, Katrin E, Cabrera Serrenho, André, Allwood, Julian M., How Will Copper Contamination Constrain Future Global Steel Recycling?, Environmental Science & Technology, 2017, doi: 10.1021/acs.est.7b00997 10.1021/acs.est.7b00997.

[100] Duscher, G., Chisholm, M., Alber, U. et al. Bismuth-induced embrittlement of copper grain boundaries. Nature Mater 3, 621–626 (2004), https://doi.org/10.1038/nmat1191.

[101] https://kupfer.de/wp-content/uploads/2020/01/Factsheet_Bismut-als-Bleiersatz_English.pdf.

Product group	Substance	CAS	Substance family	Origin/function	Materials	Intentionally and non-intentionally added substances (NIAS)	Life-cycle stage of the final product in which it is used	Description of the technical constraints (process and quality disturbing)	Source
Plastics	Carbon black	1333-86-4	Elemental carbon	Pigment in plastics	Plastic	Functional chemical	Material production	Process disturbing: The use of carbon black as a pigment in plastics can result in severe interference with the identification and separation of plastics by polymer type using near-infrared (NIR) based automatic plastic waste sorting, due to the fact that the carbon black absorbs most of the radiation, thereby making the analysis of the reflected spectrum very difficult or impossible.	Mabbett et al., 2013[102]
Plastics	/	/	Brominated flame retardants (BFRs)	Flame retardant	Acrylonitrile-butadiene-styrene (ABS), polycarbonate (PC), polystyrene (PS), polypropylene (PP), and PC-ABS	Functional chemical	Material production	Quality disturbing; The mechanical properties (tensile strength and tensile modulus) of bromine-free materials are higher than bromine-containing materials.	Lahtela et al., 2023[103]
Paper	/	/	Polymers like polyvinyl alcohol, polyvinylpyrrolidone	Substances used in adhesives	Paper	Functional chemical	Assembling, finishing, ...	Process disturbing: due to their good water solubility or re-dispersibility, they are torn into such tiny particles, that they become mechanically unsortable since they cannot be removed from the cellulose suspension	Onusseit, 2005[104]

[102] Ian Mabbett, Jon Elvins, Cathren Gowenlock, Paul Jones, David Worsley, Effects of highly absorbing pigments on near infrared cured polyester/melamine coil coatings, Progress in Organic Coatings, 2013, Pages 1184-1190, ISSN 0300-9440, https://doi.org/10.1016/j.porgcoat.2013.03.031.

[103] V. Lahtela, K. Mielonen, P. Parkar, T. Kärki, The Effects of Bromine Additives on the Recyclability of Injection Molded Electronic Waste Polymers. Global Challenges 2023, 7, 2300157. https://doi.org/10.1002/gch2.202300157

[104] Onusseit, H., The influence of adhesives on recycling, Resources, Conservation and Recycling, Vol. 46, Issue 2, February 2006, Pages 168-181, https://doi.org/10.1016/j.resconrec.2005.05.009

Product group	Substance	CAS	Substance family	Origin/function	Materials	Intentionally and non-intentionally added substances (NIAS)	Life-cycle stage of the final product in which it is used	Description of the technical constraints (process and quality disturbing)	Source
			and its copolymers polyethyloxazoline, copolyesters containing sulphonated material, hydrophilic polyurethane and polyethyleneoxide, but also starch, dextrin and cellulose						

Source: JRC's own elaboration.

In summary, the PS team is advised to assess and analyse available literature and carry out targeted stakeholder consultations in order to draft a list of substances candidate to be classified as SoCs under Art. 2(27) (d). This draft list should be shared with stakeholders in order to seek further feedback on whether the candidate substances indeed meet the criteria to be treated as SoCs under Art. 2(27) (d). Based on stakeholder feedback, and upon further investigation, the PS team should then list those substances proposed as meeting Art. 2(27) (d) criteria. The PS team could also consider organising, during the development of the Preparatory Study, specific working groups with a sub-set of stakeholders in order to discuss specific substances and in particular, substances of concern.

Finally, it should be noted that a substance which meets the criteria of SoCs (a), (b) or (c) may also qualify as a SoC (d) (via regulatory and customer-driven limitations and technical constraints) - an example might be the case of NPEOs. In such cases, the PS team is advised to give the substance the qualification related to **all** the relevant SoCs "types", i.e., **SoCs (a), (b), (c) and (d).**

Once the identification of substances of concern under Art. 2(27) (a), (b), (c) and (d) has been finalised, the data collected should be used to complement **Table 1** (from Section A) and as such, the definition of the Base Case.

Table 5 below includes columns to be completed by the PS team, noting where intentionally and/or non-intentionally added substances are involved over the life cycle of the Base Case(s), and whether they are SoCs (red columns).

Note that the format of **Table 5 is the same as Table 1**, although Table 5 refers to the Base Case and its life cycle. See **Table 1 – B and Table 5 – B**, if the simplified approach is followed.

Table 5. Summary of intentionally and non-intentionally added substances in the Base Case product and used in its life cycle (i.e. inputs and emissions) that are identified as SoCs under Art. 2(27) of the ESPR.

		Substances in the product								Substances throughout the life cyle of the product									
Component (cp_i)	**Material (m_i)**	Intentionally added substance function class (f1)	Intentionally added substance (name + CAS number)	Concentration in the material or relevant component (as available)	Identified as SoC under Art. 2(27)	Non-intentionally added substance type*	Non-intentionally added substance (name + CAS number)	Concentration in the material or relevant component (as available)	Identified as SoC under Art. 2(27)	**Life cycle process (Pi)**	Intentionally used substance function class	Intentionally used substance (name + CAS number)	Amount/ Concentration (specify if related to the relevant component, material or product)	Identified as SoC under Art. 2(27)	Non-intentionally used substance type*	Non-intentionally used substance (name + CAS number)	Amount/ Concentration (specify if related to the relevant component, material or product)	Identified as SoC under Art. 2(27)	**Details/ Comments/ References**
cp_1	**m_1**	f1 e.g. dye	m1f1ch1 e.g. TiO2			e.g. by-product				P1 e.g. raw material extraction	e.g. lubricating agent								e.g. input or emission
			m1f1ch2								e.g. dye								
			m1f1ch3																
		f2 e.g. hardener	m1f2ch1																
			$m1ch_n$							P2									
			…							…									
	m_2	f1	m2f1ch1																
			m2f1ch2																
			…																
	m(r)		…																
	m_n																		
cp_2	..		..																
…																			
cp_n																			
…																			
final product**	n.a.									P1 e.g. assembly									
	n.a.									P2 e.g. use									
	n.a.									P3 e.g. end-of-life									

Source: JRC's own elaboration.

* Specify if break-down products, impurities, side products or contaminants during the use or end-of-life stages.
** Materials and substances for final product are only in addition to those already considered in the other rows for components and materials.
Notation used: ‘cp_i’: component i, ‘m_i’: material i, ‘f_i’: function of the substance, ‘$m_i f_i ch_i$’: intentionally added substances, ‘m(r)’: recycled material; Pi (e.g., P1, P2, P3 etc): life cycle process.

Where the simplified approach is followed, only intentionally added SoCs remaining in the products under study should be reflected in such table (see **Table 5 – B** below).

Table 5 – B. Summary of intentionally added substances in the Base Case product (i.e. inputs) that are identified as SoCs under Art. 2(27) of the ESPR (simplified approach).

Substances in the product						
Component (cp_i)	**Material (m_i)**	Intentionally added substance function class (f1)	Intentionally added substance (name + CAS number)	Concentration in the material or relevant component (as available)	Identified as SoC under Art. 2(27)	**Details/ Comments/ References**
cp_1	**m_1**	f1 e.g. dye	m1f1ch1 e.g. TiO2			e.g. input
			m1f1ch2			
			m1f1ch3			
		f2 e.g. hardener	m1f2ch1			
			$m1ch_n$			
			…			
	m_2	f1	m2f1ch1			
			m2f1ch2			
			…			
	m(r)		…			
	m_n					
cp_2	…		…			
…						
cp_n						
…						
final product**	n.a.					
	n.a.					
	n.a.					

Source: JRC's own elaboration.

** Materials and substances for final product are only in addition to those already considered in the other rows for components and materials.

Notation used: 'cp_i': component i, 'm_i': material i, 'f_i': function of the substance, '$m_if_ich_i$': intentionally added substances, 'm(r)': recycled material

4.3 B3: Defining information requirements for SoCs under Article 2(27)

ESPR mandates in Article 7(5) that "information requirements [...] shall make it possible to track the substances of concern, throughout the life cycle of the products concerned, unless such tracking is already possible pursuant to information requirements laid down in another delegated act adopted pursuant to Article 4 covering the products concerned [...]".

As detailed in the same article, the information requirements for substances of concern shall include, **as a minimum**, the following:

a) *"the name or numerical code of the substances of concern present in the product [...]*;

b) *the location of the substances of concern within the product*;

c) *the concentration, maximum concentration or concentration range of the substances of concern, at the level of the product, its relevant components, or spare parts*;

d) *relevant instructions for the safe use of the product*;

e) *information relevant for disassembly, preparation for reuse, reuse, recycling and the environmentally sound management of the product at the end of its life*".

It is also stated that "The Commission may, where appropriate for the product group concerned, set thresholds for when the information requirement regarding substances of concern is to apply".

The next sections give some guidance on each of the bullet points above, discussing their implications for (i) the PS team and (ii) the operators placing a product on the market for which information requirements have been set.

Notes to Article 7(5) (a) – (e):

Article 7(5)(a) - *The name* or numerical code of the substances of concern present in the product

The ESPR mandates that manufacturers should make available information on the name or numerical code of the substances of concern present in the product, detailing their names using different nomenclatures:

- *"name(s) in the International Union of Pure and Applied Chemistry (IUPAC) nomenclature, or another international name when IUPAC name is not available;*
- *other names, including usual name, trade name, abbreviation;*
- *European Community (EC) number, as indicated in the European Inventory of Existing Commercial Chemical Substances (EINECS), the European List of Notified Chemical Substances (ELINCS) or the No Longer Polymer (NLP) list or the number assigned by the European Chemicals Agency (ECHA), if available and appropriate;*
- *the Chemical Abstract Service (CAS) name(s) and number(s), if available"*

Defining the information requirement relative to the name of the SoCs present in the product should not imply too much analysis by the PS team, given that this information, like all those listed under Article 7(5) (a) – (e) are mandatory, unless a derogation applies. <u>It is suggested that the PS team provides a list of product-relevant SoCs covered under Art. 2(27) (a), (b), (c) and (d), to the extent possible.</u> To do so, already when mapping substances in Section A, the PS team is recommended to use one of the nomenclature schemes reported above. The different names of substances may be checked via the Classification and Labelling Inventory[105] managed by ECHA. The

[105] Available here: https://echa.europa.eu/information-on-chemicals/cl-inventory-database.

Classification and Labelling Inventory is a public database, storing and displaying information on the classification and labelling for registered substances under REACH and substances notified under CLP. The database displays the name of the substance in the IUPAC nomenclature as well as the EINECS and CAS numbers, when available.

The International Union of Pure and Applied Chemistry (IUPAC) is the recognised authority on chemical nomenclature and terminology, and also develops recommendations to establish unambiguous, uniform, and consistent nomenclature and terminology for specific scientific fields. For further information on chemical nomenclature and terminology, the IUPAC Color Books or the Brief Guides to Nomenclature may be consulted.

The European Commission Inventory (EC Inventory) is composed of the following lists:

- EINECS (European INventory of Existing Commercial chemical Substances) as published in O.J. C 146A, 15.6.1990. EINECS is an inventory of substances that were deemed to be on the European Community market between 1 January 1971 and 18 September 1981. EINECS was drawn up by the European Commission in the application of Article 13 of Directive 67/548/EEC, as amended by Directive 79/831/EEC, and in accordance with the detailed provisions of Commission Decision 81/437/EEC. Substances listed in EINECS are considered phase-in substances under the REACH Regulation.
- ELINCS (European LIst of Notified Chemical Substances) in support of Directive 92/32/EEC, the 7th amendment to Directive 67/548/EEC. ELINCS lists those substances which were notified under Directive 67/548/EEC, the Dangerous Substances Directive Notification of New Substances (NONS) that became commercially available after 18 September 1981.
- NLP (No-Longer Polymers). The definition of polymers was changed in April 1992 by Council Directive 92/32/EEC amending Directive 67/548/EEC, with the result that substances previously considered to be polymers were no longer excluded from regulation. Thus, the No-longer Polymers (NLP) list was drawn up, consisting of such substances that were commercially available between 18 September 1981 and 31 October 1993.

The Chemical Abstract Service (CAS) or Registry Number is a unique and unambiguous identifier for a specific substance that allows communication and links all available data and research about that substance.

Article 7(5)(b) - The location of the substances of concern within the product

The information requirement on the location of the SoCs within the product refers to the component, material and/or mixture in which the SoC is contained.

The analysis contained in the Preparatory Studies should try to identify, to the extent possible, which substances of concern, among those listed in Section A, are present in the different materials and components of the product under consideration. It should also identify substances incorporated in the product as part of a chemical mixture that is, for instance applied onto the product, e.g. some finishing process for textiles or coatings applied to furniture, or adhesives used to glue different layers in absorbent hygiene products. It should be noted that the purpose-specific information collected in **Table 1** should already provide information regarding which substances are included in specific materials and/or components.

Additionally, beyond the minimum mandatory scope established under Article 7(5)(b), it may also be useful for the PS team to highlight substances that are contained in parts of the product which are in direct contact with consumers during reasonably foreseeable use conditions. Similarly, it would be useful to have an indication of whether the SoCs are bound in a matrix, with minimal risk of spillage or leaching, or whether they are instead contained in an unbound manner (e.g. in a bulk deposit or container). Publicly available documents may help in the identification of such substances as well as the quantification of their release, according to the chemical and physicochemical properties of the substance, the type of matrix and the foreseeable use, for example, the ECHA guidance on consumer exposure estimation[106], the EFSA guidance on food contact materials[107], and the OECD publication on emissions of plastic additives[108]. These issues may influence the type and extent of information to be declared by the manufacturers, e.g. fragrances applied onto a tissue paper vs flame retardants in electrical and electronic equipment (as already referred to in as useful information to collect in Section A).

Article 7(5)(c) – <u>The concentration, maximum concentration or concentration range of the substances of concern, at the level of the product, its relevant components, or spare parts</u>

This information requirement refers to the disclosure of information on the concentration of SoCs within the product, its components or its spare parts.

The analysis contained in the Preparatory Study should collect available information on the typical concentrations of substances of concern in the products under analysis. This is particularly relevant in terms of obtaining a better understanding of the incidence of SoCs in products in view of considering, as appropriate, actions to establish risk management measures, to enable informed consumer choices, for the purpose of more effective waste management (e.g. *via* adaptation of waste treatment processes, EPR ecomodulation, etc.).

The task of the PS team should be to determine if the delegated act for a given product might require operators to disclose information on SoCs in terms of exact concentrations, maximum concentrations or concentration ranges. In doing so, due account should be taken regarding legitimate claims on protection of confidential business information (CBI), and also the extent to which it is feasible for the economic operator to gather such knowledge.

For substances of concern that are not intentionally added to the product (e.g. products formed via chemical breakdown, impurities, side products or incidental contamination), providing such information on concentration levels could be very challenging. This is because manufacturers may not be in a position to obtain such information without resorting to extensive laboratory tests or engaging with perhaps a long “upstream” supply chain. In addition, there may be cases where suitable analytical methods are not available for detecting and quantifying the presence of certain substances in some matrices.

Where information is difficult to obtain, the developers of Preparatory Studies may consider proposing as part of the proposed information requirements that the economic operator solely needs to disclose the maximum expected concentration of a substance of concern in the product and in the relevant component, rather than the concentration range or exact concentrations.

Case-by-case considerations on the disclosure of SoCs concentration should always apply, because the possibility to disclose information on the precise concentration of a substance of concern will depend heavily on the product’ specificities and its supply chain.

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[106] ECHA, 2009. Guidance on information requirements and chemical safety assessment. Chapter R.15: Consumer exposure estimation. https://echa.europa.eu/documents/10162/23047722/r15_update_version_2_rev20_en.pdf/ea08eca8-c0f9-41a0-9a3f-fdab925151b1.

[107] EFSA, 2020. Guidance for the preparation of an application for the safety assessment of a substance to be used in plastic food contact materials. https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2008.21r.

[108] OECD, 2019. Complementing document to the emission scenario document on plastic additives: plastic additives during the use of end products. https://www.oecd.org/en/publications/complementing-document-to-the-emission-scenario-document-on-plastic-additives-plastic-additives-during-the-use-of-end-products_1f74e9e4-en.html.

Article 7(5)(d) – <u>Relevant instructions for the safe use of the product</u>

This information requirement refers to the providing of information to the user to ensure the product's safe use. In this context, the aim of safe use instructions is understood in alignment with REACH Art. 33.1, but not limited to solely SVHCs, since all the SoCs should be considered. In addition, in the context of the ESPR, safe use should only refer to the use stage and the foreseeable use of the product.

An analysis of the foreseeable uses of the product would be carried out in Task 3 of the MEErP. Such an analysis should then investigate whether, during the use stage of the product, there could be uses that may potentially lead to the release of SoCs and to resulting risks for the user (e.g. skin or respiratory irritation, intoxication, etc.) and the environment (effects on aquatic or terrestrial organisms, effects on the ozone layer, etc.), as anticipated for the analysis for setting requirements according to Article 7(5)(b). An example could be the handling of products containing batteries, which, if not handled as prescribed by the manufacturer, could lead to important contamination risks. This also includes safe disposal of batteries by consumers. With specific regard to SVHCs (a particular group of SoCs within the meaning of Art. 2(27) of the ESPR) a specific source of this information is REACH Art. 33 and the associated ECHA Guidance[109], where reference to safe use information is made. According to the potential for release and exposure to SoCs under foreseeable use, a qualitative description of the risk could be considered sufficient, together with the instruction on how to properly handle the product.

Relevant information about substances of concern to be provided by the manufacturers of the final product, in addition to the composition of the product in terms of SoCs, may include:

— Product parts entailing a specific risk for the user and/or the environment (considering possible emissions or leakages during use stage);

— Other products, materials and/or substances that are incompatible with the product (e.g. consumables or spare parts which could also be subject to leaks/emissions if not compatible and intended to use);

— How to identify whether the product is broken or is no longer fulfilling its function as it should (especially for complex articles).

The PS team should analyse which of the above information is relevant to be subject to information requirements, and if additional elements of information requirements should be considered.

Article 7(5)(e) – <u>Information relevant for disassembly, preparation for reuse, reuse, recycling and the environmentally sound management of the product at the end of its life</u>

This information requirement refers to the provision of information to the user and/or other relevant actors, with regard to how to handle the product at the end of its life (EoL).

The analysis in the Preparatory Study should investigate the possible options of repair, reuse, recycling or otherwise disposal regarding the product. The PS team should identify important procedures that should be followed in order to ensure safe and environmentally sound product EoL management (this is also included in other parts of the method to define ecodesign criteria). Layers/materials in the product that become available only to recyclers/repairers once the product reaches its EoL should also be identified, together with any substances of concern included in such layers/materials. To do so, sufficient attention should be placed in the Preparatory Study regarding the level of complexity of the product, as well as to how recycling/repair is usually carried out. The

109 ECHA, 2017. Guidance on requirements for substances in articles. Version 4.0. https://echa.europa.eu/documents/10162/2324906/articles_en.pdf

PS team should identify whether, due to the presence of SoCs therein, there could be risks for workers during the EoL operations/ processes, for example, releases of substances of concern which cause harm via, for example, skin or respiratory irritation, intoxication, etc. Similarly, the PS team should assess the potential risks to the environment (effects on aquatic or terrestrial organisms, effects on the ozone layer, etc. due to leakages and emissions). These analyses should be performed in close collaboration with relevant stakeholders, in particular industry stakeholders, waste managers, environmental NGOs and consumer associations (as discussed in Section A). With specific regard to disassembly and SVHC, it may be useful to consult the available ECHA guidance on requirements for SCIP notification[110].

Relevant information requirements build on current best practice in product-specific "daughter" regulations from the Ecodesign ErP 2009 Directive, and may include (in text and/ or diagrammatic form):

- How to dismantle, repair or recycle the product;
- The identification of parts that can be dismantled from those that cannot;
- Product parts entailing a specific risk for the worker and/ or the environment (considering possible emissions or leakages during end-of-life stage);
- The tools that should be used to dismantle the product;
- Whether dismantling of the product should be carried out only by professionals;
- The identification of parts that should be removed prior to any dismantling, preparation for reuse, reuse or recycling;
- Any protective equipment that should be used when using, handling, dismantling or recycling the product.
- Disposal instructions (separate collection obligations, forbidden or disadvised disposal options, etc.)
- List of substances required for carrying out the operations for disassembly, preparation for reuse, reuse, recycling of the waste and if they are SoCs.

Substances of concern throughout the life cycle of materials and products

Process substances which are SoCs, resulting in relevant emissions throughout the life cycle of the product may, as appropriate, be included as information in the Digital Product Passport (DPP), depending on the nature and potential impact of such emissions. Such an assessment should be performed on a case-by-case basis, taking into account relevant applicable emission limit values and guidance.

Thresholds

The PS team should identify and establish the minimum concentration thresholds that trigger compliance with information requirements (i.e. concentration values below which substances of concern do not need to be tracked). As such, the structure for this section is presented below:

- General suggestion for thresholds ensuring consistency with other horizontal Union legislation;

[110] ECHA, 2020. Requirements for SCIP notification. Version 1.0 https://echa.europa.eu/documents/10162/6205986/information_requirements_for_scip_notifications_en.pdf/db2cf898-5ee7-48fb-e5c8-4e6ce49ee9d2?t=1615368638768

- The possibility to set specific thresholds (stricter than those set by regulatory requirements mentioned in the previous point);
- Other references that can be used where there is no data available.

When a substance is assigned to more than one SoC category (e.g. a SoC which is both type a) and d)), the threshold triggering the information requirement should conservatively be defined considering the lowest value among the criteria identified for the different SoCs.

Generic approach to thresholds

Information requirements should be applied at the level of and above thresholds of the SoCs (a, b, c, or d).

As mentioned in **Article 7(5)**, '*The Commission may, where appropriate for the product group concerned, set thresholds for when the information requirement regarding substances of concern is to apply'*. To ensure the uniform implementation of information requirements, it is suggested that the PS team proposes thresholds for the substances of concern covered by such requirements. Within this method, it seems appropriate to suggest aligning the threshold for information requirements for safety-related SoCs (i.e. those under Art. 2(27) (a), (b) and (c) with relevant thresholds established in other Union legislation. In particular, it is proposed to:

- For **SoCs under Art. 2(27) (a) and (c)** present in products that are articles (according to REACH definition provided by Art. 3.3), it is suggested to set a threshold of 0.1% w/w, in line with the information obligation for substances of very high concern in articles according to Article 33(1) of REACH. For SVHCs present in products that are substances or mixtures, the same thresholds of 0.1% is proposed to be applied[111]. Equally, all POPs are proposed to be treated as if they were listed as SVHCs in the Candidate List and therefore a threshold value of 0.1% is also proposed to be applied for the purpose of proposing the triggering the information requirement for POPs contained in products in scope of the ESPR delegated acts (both for articles and for products which are substances and mixtures).
- For **SoCs under Art. 2(27) (b) a differentiated approach may be considered, depending on whether the product in scope is a substance / mixture or an article:**

  (1) for **SoCs under Art. 2(27) (b) in products within the scope of the ESPR <u>which are substances and mixtures,</u>** it is suggested to set a generic threshold equal to the concentration limits in Table 1.1 of Annex II to REACH, which refers to substances that should be listed in the safety data sheets of mixtures classified as hazardous according to CLP. Where a relevant hazard class or category is not listed in the referred table, but appears in Annex I to the CLP Regulation with a generic concentration limit (GCL), as applicable for the classification of mixtures, the lowest generic concentration limit value for the substance in that class/category will be will be used that leads to classification of the mixture (i.e. in the lower category of the relevant hazard class), to the extent this information may be available. This approach is inspired in the requirements defined in Annex II to REACH as regards the constituents that have to be identified in mixtures

[111] This is largely in line with the requirements set in Annex II to REACH (as regards thresholds for reporting SVHCs which are PBT, vPvB or presenting an equivalent level of concern, such as endocrine disruptors) and to the generic concentration limits applicable to the classification of mixtures, in Annex I to CLP, for carcinogens and mutagens of Cat 1A and 1B, for endocrine disruptors of Category 1 as well as for PBT substances, vPvb substances, PMT substances and vPvM substances.

classified as hazardous but where, for greater ease of application for the purposes of the ESPR, the full array of criteria defined in its section 3.2.1. are intentionally omitted.

(2) for **SoCs under Art. 2(27) (b) in products <u>which are articles</u>**, it is suggested to set a generic threshold equal to the cut-off values in Table 1.5.1 provided under section 1.5.3. on "General guidance for compiling safety data sheets" of GHS[112]. These values indicate the minimum information on hazardous constituents that should be available, internationally, in all SDS produced in compliance with GHS. Note that the hazard code 'hazardous to the ozone layer' is not listed in Table 1.5.1 of GHS, however this hazard is defined in Chapter 4.2 'Hazardous to the ozone layer' of GHS and therefore it is proposed to use the concentration of 0.1% which is used for the classification of mixtures in the Montreal Protocol. This 0.1% applied to the hazard class 'hazardous to the ozone layer' is in line with Table 5.1 of Annex I to CLP and with Table 1.1 of Annex II to REACH (classification limit for mixture classification). Where a relevant hazard class or category is not listed in the referred table, but appears in Annex I to the CLP Regulation with a generic concentration limit (GCL), as applicable for the classification of mixtures, the lowest generic concentration limit value for the substance in that class/category will be will be used that leads to classification of the mixture (i.e. in the lower category of the relevant hazard class)[113], to the extent this information may be available.

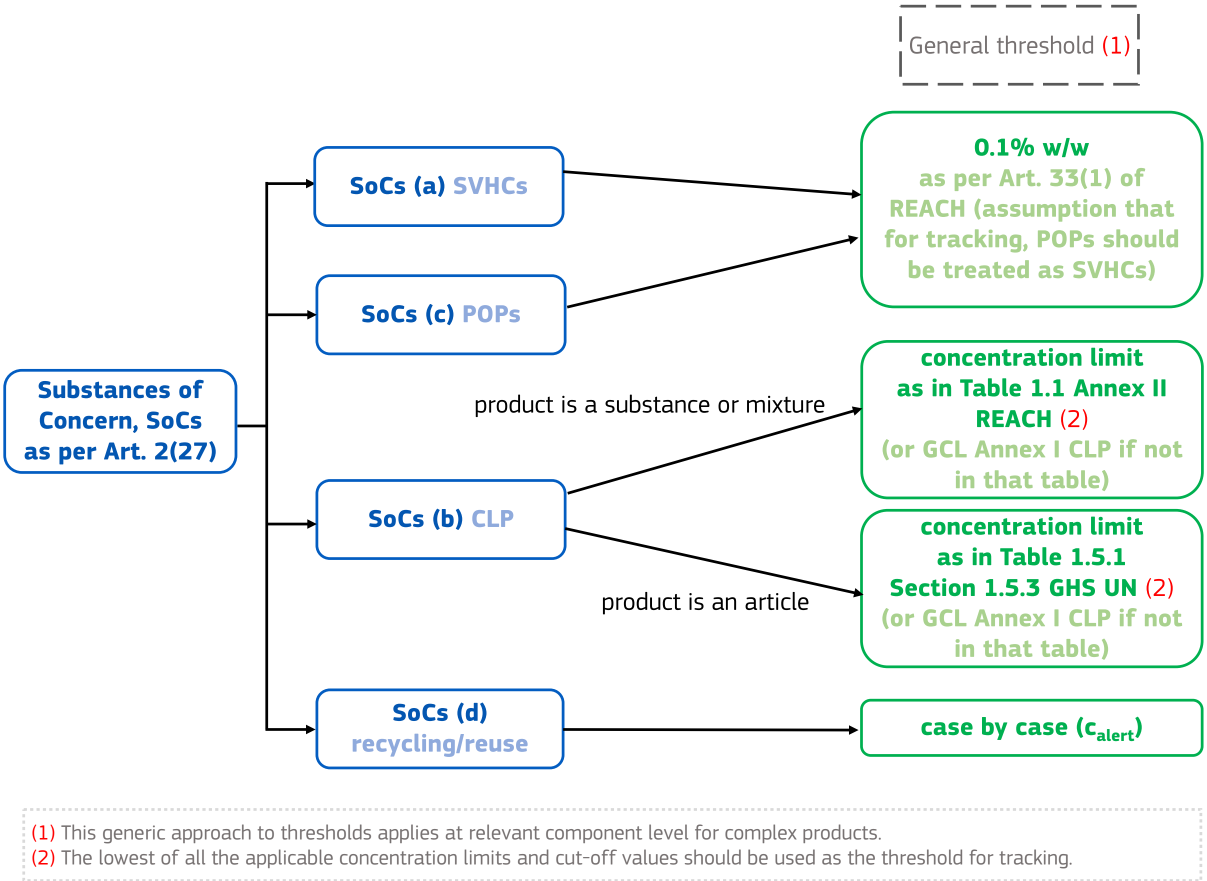
Depending on product or sector specific considerations, such as the market share of product manufactured outside the EU being small – therefore increasing the likelihood of availability of REACH compliant SDS for mixtures used in its production - or based on other justified considerations, the Preparatory Study team may consider the appropriateness of deviating from the above approach, also proposing option (1) for defining the thresholds applicable to SoCs (b) in products which are articles.

— It is suggested that for **SoCs under Art. 2(27) (b)** the lowest of all the applicable concentration limits and cut-off values (corresponding to the hazard classes applicable to the substance) is used as the threshold for tracking. It is further suggested that the Preparatory Study team compiles all relevant thresholds proposed in a table, for potential inclusion in delegated act for the product, so as to increase clarity and legal certainty for all actors.

[112] Globally Harmonised System on Classification and Labelling of Chemicals (GHS). Tenth revised edition. United Nations 2023. https://unece.org/transport/dangerous-goods/ghs-rev10-2023

[113] For instance, it could happen that a mixture is classified under Category 1 for a given hazard class when a 1% GCL value of a substance is applicable but that mixture is classified as Category 2 when a GCL of 0.1% is reached. In this case, the lowest value, i.e. 0.1% should be considered for that substance (because the lowest concentration would lead to the classification of the mixture and, therefore, should still be mentioned in the SDS).

Figure 6. Generic approach to thresholds. Notation used: CLP: Classification Labelling and Packaging Regulation; GCL: generic concentration limits; GHS: globally harmonised system; POPs: persistent organic pollutants; REACH: Regulation for the Registration, Evaluation, Authorisation and Restriction of Chemicals; SoCs: substances of concern; SVHCs: substances of very high concern.



Source: JRC's own elaboration.

As regards the application of the proposed thresholds for all substances of concern, under the ESPR, at the level of products and their relevant components, the Preparatory Study team is advised to consider and propose a calculation approach, indicating the required level of granularity, taking into account provisions in the ESPR legal text which provide a certain degree of liberty, the applicable jurisprudence and as applicable considerations of feasibility and proportionality.

Also to be taken into account is the issue that for the purposes of substances identified as SoCs (a) (SVHCs), the supply chain information obligations defined in REACH Article 33 currently apply to the definition of "article" under article 3(3) of REACH and thereby must be applied according to the ruling of the European Court of Justice on the application of the 0.1% threshold (Case C-106/14). This is already an applicable legal obligation to be considered, but the PS Team is advised to ensure they take into account the latest available and consolidated version of the REACH legal text. Note that, at the time of drafting this guidance document (June 2025), REACH was in the process of being revised.

When the product is made of different components (NB not the case for mixtures or for intermediate products, which are "assumed to be homogeneous" in their composition), the concentration of the SoC, if related to the overall weight of the complex product, will be lower, to a greater or lesser extent, than where the concentration refers to the component - depending on the ratio of the weight of the component to that of the final product.

If these recommendations are retained by the PS team for a specific product group, this would mean that the economic operator would be required to disclose the concentration of the SoC with respect to: the product, or its relevant components, or spare parts (as stated in Art 7(5)(c) of the ESPR). Note that, for relevant components and spare parts, this applies even when the concentration of the SoC in the (complex) product is lower than the generic thresholds defined above.

For products that <u>do not</u> include components, as well as regarding products that are mixtures, the minimum concentrations for complying with ecodesign information requirements would be the **generic** thresholds above, applied at the level of the product. (*Note that the ECHA "Guidance on requirements for substances in articles"*[114] *is a useful source as to how the 0.1% threshold applies in REACH, and contains elements which could potentially also be considered for the purposes of the ESPR.)*

The use of the proposed thresholds for SoCs under the ESPR Article 2(27) (b) in mixtures would ensure that the information requirements for SoC under the ESPR are broadly consistent with - and can be fulfilled by - referring to the product Safety Data Sheets (SDS) produced to comply with Annex II to REACH. These SDS apply to substances and mixtures that have been produced in the EU, or imported into the EU (and thus placed on the EU internal market), which are required to have an SDS via Article 31(1)[115] of REACH.

Note that this recommended approach in no way weakens the duty to provide information for the safe use of chemicals required under REACH and provided via SDSs, which are mandatory for all substances and mixtures placed on the market in the EU that meet the requirements in Article 31(1) of REACH. The approach proposed is also consistent with the provision in Article 7(3) of the ESPR that states that "*Information requirements based on the product parameter set out in Annex I, point (f), shall not concern the labelling of substances or mixtures for reasons relating primarily to their hazards to health or the environment*.").

<u>*Note for Preparatory Study practitioners*</u>

Whenever possible, the PS team should try to obtain as much information as possible on the presence and concentration of substances of concern in products, their components and spare parts. The PS team can use as a starting point the analysis explained in Section A, **Table 1**), regarding **information on the concentration, maximum concentration, or concentration range** of substances of concern in products, relevant components and spare parts can help the PS team to understand how a specific substance of concern is used in specific products and how such concentration data compare to the generic threshold proposed above, aside from the use of this information in the assessment to be taken forward for possible proposals on information requirements according to ESPR Article 7(5)(c). Any potential proposals for thresholds triggering information requirements should be checked with stakeholders via consultation.

SoCs under Art. 2(27) (d) represent a special case, since they are SoCs owing to their chemical safety *per se*, but also primarily because of their physio-mechanical-chemical properties or their capacity to hinder reuse or recycling. For such substances, a fully substance-specific approach is needed, as proposed in the next section.

Substance-specific approach to thresholds

For Substances of Concern for which a specific regulatory or supply-chain driven requirement exists for a specific substance or family of substances, it is advised to take into consideration a

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114 ECHA, <u>Guidance on requirements for substances in articles</u> - Version 4.0, June 2017

115 Article 31(1) The supplier of a substance or a mixture shall provide the recipient of the substance or mixture with a safety data sheet compiled in accordance with Annex II: (a) where a substance or mixture meets the criteria for classification as hazardous in accordance with Regulation (EC) No 1272/2008; or (b) where a substance is persistent, bioaccumulative and toxic or very persistent and very bioaccumulative in accordance with the criteria set out in Annex XIII; or (c) where a substance is included in the list established in accordance with Article 59(1) for reasons other than those referred to in points (a) and (b).

substance-specific threshold approach in recommending thresholds above which tracking should be required. This involves two main cases:

- SoCs under Art. 2(27) (d);
- SoCs under Art. 2(27) subject to relevant legal restrictions in products.

SoCs under Art. 2(27) (d) represent a class of substances of concern defined for the first time under the ESPR to address the possibility of substances that hinder the circularity (including recycling) of products. For such substances, a list of substances to be tracked will be proposed for each delegated act and will be specific to the product(s) under analysis.

Given the specific nature of SoCs under Art. 2(27) (d), it is not suggested to apply generic thresholds; rather, it is recommended to establish thresholds based on the information collected *via* stakeholder consultation among recycling/reuse companies, as well as literature sources. The data to seek are related to concentrations of identified SoCs under Art. 2(27) (d) that interfere with the recycling or preparation for reuse processes and on the quality of the recyclate, i.e. the **alert concentration** (c_{alert}) **for technical constraints** as defined in this document, Section B2.

This "alert concentration" for technical constraints is intended to be the concentration indicated by recycling companies, and derived from considering other relevant sources, that may lead to disposal of the waste via incineration or landfill. That is, indications from recycling companies and related feedback/ literature show that it may not be feasible to manage and reduce the waste via pre-treatment processes prior to any recovery or recycling processes. In other words, because of these issues/ complications it is likely that the materials would never reach a recovery or recycling plant or processes. The adoption of the alert concentration for triggering information requirements would enable the collection of data on the typical concentration of SoCs under Art. 2(27) (d) used in the product.

Substances of concern subject to legal restrictions in products include specific restrictions under REACH or the POP Regulations for a substance in a given material or article type (e.g. restrictions 51 and 52 in Annex XVII to REACH referring to certain phthalates). Other examples include substances in Commission Directive (EU) 2021/903 establishing specific limit values for aniline (classified as "carcinogenic category 2" and "mutagenic category 2"). This restriction is applied to certain toys, at the level of 10 mg/kg as free aniline in finger paints (which is lower than the 10 000 mg/kg limit established under the CLP Regulation for the purpose of classification of mixtures containing aniline).

Where there is a legal SoC restriction stemming from other legislation (e.g., the Toys Directive), a case-by-case assessment should be made to assess the relevance of a product specific limit, to the overall destination market for recycled material potentially affected. This assessment has to determine whether the legal limit relevant to the substance in the product-specific legislation may be relevant for the particular recyclate stream.

In general, the case of **substance of concern restricted in other (non-ESPR) product regulations** implies that no products for the respective restricted applications should be present in the EU market containing concentrations above the limit value, unless derogations exist for such restrictions. This consideration opens up to two possible approaches for the setting of specific thresholds (hereafter referred to as **c_{alert} for regulatory limitations**):

- Propose a threshold that is lower than the restriction limit value set in the applicable EU legislation (i.e., from another regulatory area), with the purpose of tracking the presence and concentration of such substances in products, including at concentrations below the restriction limit value. In order to ensure the enforceability of the information requirement, the PS team should investigate and ensure that any proposed threshold can be measured in products and/or components, and in the appropriate matrices (e.g. plastic, textile fibres, wood, etc.). Thus, the tracking threshold should always be higher than the Limit of Quantification (LOQ), to be studied on a case-by-case approach. Furthermore, a suitable analytical method should be widely available for the reliable quantification of the substance (see also the next section on exemptions). Stakeholders' feedback will be extremely important to determine this aspect.

— Propose an exemption from the information requirement for restricted substance(s) in the cases where the restriction limit is lower than or equal to the generic threshold proposed in the section above. Given that the substance is already banned (via the other applicable legislation), or in principle should not be present above the required concentration (where it has not been banned, but otherwise is subject to a maximum concentration) in products in the EU market, ESPR-related tracking of such substances could – depending on the considerations made when setting the restriction limit - be considered unnecessary. As such, the substance could therefore be exempted from any tracking obligations under the ESPR. Where derogations from other legislation exist (i.e., where the substance is not exempt from those other regulations), the substance must till therefore be tracked, and it is proposed to adopt the applicable generic threshold proposed in the previous section.

The substances falling under the above situations will require case-by-case assessment within each individual Preparatory Study, or in the subsequent Impact Assessment supporting the delegated act, with regard to proposing the setting of requirements for the product. The choice of one approach over the other is likely to be very product-, substance- and restriction-specific. One approach ensures that tracking takes place also for substances restricted in products while the second approach represents a simplified solution, which would avoid setting very low thresholds (which may in some cases be impossible to detect and track. **It is in any case suggested that both approaches are proposed and assessed, overall, as part of the Impact Assessment following the completion of the Preparatory Study.**

When information is available on thresholds for specific substances of concern that have been proposed for information requirements in other ESPR Preparatory Studies for other product groups, when these have similar life cycle stages and functions to the ones under consideration, these could be also considered.

In addition to the points above, it is important to note the possibility of overlaps, for the same substance, between thresholds applicable with regard to SoCs (a), (b), (c) and (d). It could be the case that a substance identified as a SoC under Art. 2(27) (b) is proposed also as a SoC under 2(27) (d) because of e.g. a regulatory or customer-driven limitations. When this occurs, it is important that the substance is identified under all applicable definitions, and the full information should be reported by the PS team during the Preparatory Study. However, in the context of setting thresholds, it is important to clarify that **the strictest threshold should apply**.

Where the substance and threshold identified for a SoC (d) comes from a customer-driven specification, (hereafter referred to as **c_{alert} for customer limitations**), the threshold identified for triggering such a limitation should be investigated further to demonstrate that it constitutes an actual barrier to circularity, e.g., via evidence collected from stakeholders during consultations, upheld where possible by literature/ feedback from technical inspections from Member States' ministries, inspectorates or agencies, etc.

Exemptions

In a simplified broader approach towards exemptions, different levels of ambition could be potentially set and assessed at the IA stage, when tested as policy options. For possible alternative scenarios (1 to 3), the level of ambition in relation to exemptions to tracking could be reduced, if duly justified

Art. 7(6)(b) of the ESPR states that “where the Commission sets out information requirements in a delegated act adopted pursuant to Article 4, it shall, where relevant: [...] (b) provide duly justified exemptions for substances of concern or information elements from such information requirements referred to in the first subparagraph of paragraph 5, based on the technical feasibility or relevance of tracking substances of concern, the existence of analytical methods to detect and quantify them, the need to protect confidential business information or in other duly justified cases; substances of concern within the meaning of Article 2(27), point (a), shall not be exempted if they are present in products, their relevant components or spare parts in a concentration above 0.1 % weight by weight”.

The PS team should collect information about possible exemptions from stakeholders during public consultations. It is recommended that two stakeholder consultations take place during the Preparatory Study development where information on exemptions should be collected as well as other feedback. In the first consultation, proposals for exemptions should be collected from any stakeholder involved in the process. In the second consultation, feedback on the proposed exemptions should be used to confirm the proposals which may already be pre-selected by the PS team from the information received in the first consultation. There should be another consultation at the IA stage, where the costs and benefits of the proposed information requirements and exemptions, as estimated by the IA team, should be verified with stakeholders, to the extent possible.

The paragraphs below addresses the main product- and substance- specific aspects, mentioned in the ESPR legal text that should be considered when setting exemptions on information requirements for substances of concern (technical feasibility, relevance of tracking of substances of concern, existence of analytical methods to detect and quantify substances of concern, need to protect confidential business information (CBI) and other duly justified cases for exemption from information requirements).

Technical feasibility

This aspect refers to the technical limits to which substances can be tracked in a product, its relevant components, or spare parts due to e.g. the complexity of the value chain and/or the waste chain operations, or where there are insufficiently detailed data, or data sources.

For this aspect, the PS team should rely on the research carried out in Section A on the **supply chain of the product, its relevant components, or spare parts**, in order to identify whether significant issues arise that impede the knowledge transfer along the supply chain. A relevant example is the provision of information on substances used in the inks and dyes applied to absorbent hygiene products; this is challenging for manufacturers to obtain, because of the long value chain involved[116]. In order to decide on this aspect, feedback from relevant stakeholders during the Preparatory Study will be extremely important, including with regard to the availability and implementation level of supply chain transparency systems and tools.

Relevance of tracking of substances of concern

This aspect refers to whether there may be cases for which tracking the presence of (specific) substances of concern is not needed. This may be linked to whether substances are present in concentration below the cut-off thresholds identified above, or whether substances degrade during processing and are not present anymore in the final product, or if the substance is destroyed during “normal” recycling processes (e.g. traces of oil on or in steel products).

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[116] Faraca, G., Perez Camacho, M.N., Lag Brotons, A., Perez Arribas, Z., Kowalska, M.A. and Wolf, O., Revision of EU Ecolabel criteria for Absorbent Hygiene Products and Reusable Menstrual Cups (previously Absorbent Hygiene Products), Publications Office of the European Union, Luxembourg, 2023, doi:10.2760/209936, JRC134197.

It is also important to consider where the tracking of substance may not be relevant, owing to the substance is “locked” inside in a certain matrix, making it unlikely to be released. Again, this requires the PS team to conduct a careful case-by-case assessment, on a substance- and matrix-specific basis, suitably supported by suitably rigorous stakeholder feedback and scientific evidence, to enable the successful demonstration of the lack of, or very low availability/leachability of the substance in the applicable, carefully defined conditions. Well-known examples include nickel or chromium present in the form of an alloy, e.g. in stainless steel. It is worth noting that for such cases, available information related to the specific risks posed by substances present in such specific materials should be considered.

NB It should also be well noted that such *risk-based considerations*, associated with substances remaining tightly bound within matrices, **may not be fully relevant** when assessing impacts during the waste management stage, where the discarded products are often shredded, ground, heated, etc. for the subsequent treatment stages (*which may result in the release of the substances, as powders, vapours, etc.)*.

As stated in the ESPR, the Digital Product Passport (DPP) should be user-friendly and include accurate, complete and up to date information. Exemptions from the tracking requirements for SoCs, based on relevance, could also be set for those substances that, based on experience and feedback, are known not to be foreseeably present in a given product group, in order to reduce the administrative burden on the value chain. This also helps to simplify the work for industry, but still requires thorough analyses by the PS team in order to propose any such “lists of exempted substances” per product group. Setting such a list would require also a revision mechanism with a certain periodicity: (i) in order to avoid that newer SoCs are overlooked; (ii) so that any potential product design or technology updates may be addressed, or perverse incentives corrected. In addition, there could be cases when the lack of relevant exemptions is not “per substance” but rather for some specific information elements listed under Article 7(5). For instance, information on safe use (point d of Art. 7(5)) and disassembly, reuse, recycling and the environmentally sound management of the product at end-of-life (point e of Art. 7(5)) may be pertinent for (some) substances in consumer products, but may not be relevant for intermediate products which are handled in a professional / industrial environment or where, for instance, matrix effects may also largely limit exposure.

Other aspects, such as location of the SoCs within products, as well as concentration, maximum concentration or concentration ranges (Art. 7(5) b and c respectively) in parts of the product may not be necessary for simple and/or homogeneous products. These aspects are also applicable when considering intermediate products but are probably less applicable to final products.

Other **sector-specific exemptions** to tracking SoCs (b) or (c) should automatically apply, where these are reported. Sector-specific exemptions to tracking SoCs (a) should be carefully assessed against their compliance with ESPR Article 7(6) (b). There could be cases when the tracking of a substance is determined as being **not relevant,** owing to the existence of exemptions in other regulatory instruments. Examples include those substances from the RoHS and the POPs Regulations, as described below.

RoHS Annex III and Annex I to the POPs Regulation, which specify the following exemptions for unintentional trace contaminants (UTC) for (i) semi-finished products or articles, or parts (<0.1% by weight or <0.01% by weight for certain substances regulated under RoHS) and (ii) substances or preparations (<10 mg/kg or 0.001 % by weight) for POPs. According to Art. 4(1) and Annex II to RoHS, lead (Pb), mercury (Hg), cadmium (Cd), hexavalent chromium (Cr^{6+}), polybrominated biphenyls

(PBB) and polybrominated diphenyl ethers (PBDE) are limited to a concentration <0.1% by weight (except Cd <0.01% by weight) in homogeneous materials[117].

However, the Annex III to RoHS, lists the exemptions to the application of the cited article for many of these substances and for instance, Hg in lamps if certain conditions apply, Pb in certain capacitors or Cd in some alloys. Annex I to POPs Regulation provides a summary of the specific exemptions on intermediate use and other specifications which includes over 30 entries (at the time of writing this report) applicable to POPs in products such as electrical and electronic equipment, aircraft or motor vehicles.

The existence of analytical methods to detect and quantify substances of concern

This aspect relates to the options that product manufacturers or suppliers have, in order to obtain information on the presence and concentration of substances of concern in their product/component/spare parts, via their value/ supply chains.

Although information on the presence of a specific substance may be communicated, e.g., via "upstream" suppliers to the manufacturer of the product via SDSs (for substances and mixtures), product technical sheets or other means, sometimes this information is challenging to obtain, including the relevant concentrations of substances. For example, it may be challenging to analytically determine the concentration of such a substance in the product, especially given the substance will have often undergone processes such as mixing, dilution or reaction, in the product. This may be the case of reactive dyes used in textiles, which once used to dye a fibre, form a covalent bond becoming part of the fibre itself, and hence it is difficult to analyse the individual "substances" part of the dye, for example, the halogens or vinyl compounds.

Consequently, the following elements are all important for the PS team to understand, as far as is feasible, in the time dedicated to a Preparatory Study, to ensure that the requirements proposed are proportionate for a given SoC: the availability of harmonised or non-harmonised analytical methods, standard operating procedures, reference standards, as well as the nature and sophistication of analytical equipment required, the time scale of the analysis, analytical sensitivity, availability in commercial service laboratories in certain regions in the globe, etc.

The above considerations may be of relevance especially for substances of concern that occur as impurities in the final product, and whose presence cannot be 'calculated', and may need to be determined by means of laboratory analysis. The developers of Preparatory Studies should therefore to the extent possible investigate the state of the art of technologies and analytical methods for the analysis of substances in the final product and in different stages of its manufacturing process and service life including substances added in the end-of-life. In addition, the economic implications of performing such tests for different actors in the market should be investigated to the extent possible. Information regarding available analytical methods for specific substances and restricted substances may be found in the literature and in databases, as well as in compilations of analytical methods made by organisations such as ECHA. A non-exhaustive list of sources is as follows:

— Compendium of Analytical Methods recommended by the Forum to check compliance of REACH Annex XVII restrictions[118];

117 Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment, https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02011L0065-20160715.

118 ECHA 2021. https://www.echa.europa.eu/documents/10162/13577/compendium_of_analytical_methods_en.pdf/4c730fb9-1b48-2e14-6ee3-7a36391b7322.

- List of analytical methods used by European customs laboratories[119];
- ECHA CHEM database[120] – information on analytical methods is often available in REACH registration dossiers;
- OECD eChemPortal[121];
- PubChem[122] – analytical methods available under section 10 "identification" of substance information retrieved from the database;
- US FDA Foods Program Compendium of Analytical Laboratory Methods[123];
- US EPA. Hazardous Waste Test Methods / SW-846[124];
- US EPA Pesticide Analytical Methods – Environmental Chemistry Methods[125];
- Official Standards: ISO, CEN, ASTM International, etc.;
- Service catalogues of commercial analytical laboratories.

The need to protect confidential business information (CBI)

In addition to what is stated in Article 7(6)(b) on exemptions, **Article 5(10) d** requires the Commission to take into consideration the protection of confidential business information when preparing ecodesign requirements[126]. The ESPR text, however, does not provide further indications of what constitutes confidential business information, nor how this can be claimed. Also, the ESPR does not explicitly indicate the following balance: how the legitimate interests of the owners of the information regarding a product and, in this case, its composition, should be weighed compared to the public interest for disclosure, and consumers' right-to-know.

According to Directive (EU) 2016/943[127] on the protection of undisclosed know-how and business information (also called "trade secrets") against their unlawful acquisition, use and disclosure, a 'trade secret' means information which meets all of the following requirements: (a) it is secret in the sense that it is not, as a body or in the precise configuration and assembly of its components, generally known among or readily accessible to persons within the circles that normally deal with the kind of information in question; (b) it has commercial value because it is secret; (c) it has been subject to reasonable steps under the circumstances, by the person lawfully in control of the information, to keep it secret[128].

It should be noted that Article 3(2) of Directive (EU) 2016/943 states that "the acquisition, use or disclosure of a trade secret shall be considered lawful to the extent that such acquisition, use or disclosure is required or allowed by Union or national law", making it thereby necessary to closely consider the mandatory nature of information requirements in ESPR, for which derogations can be provided in the applicable delegated act.

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119 https://taxation-customs.ec.europa.eu/system/files/2022-02/ILIADe_List-Analytical-Methods_January2022.pdf.

120 https://chem.echa.europa.eu/.

121 https://www.echemportal.org/echemportal/substance-search.

122 https://pubchem.ncbi.nlm.nih.gov/.

123 https://www.fda.gov/food/laboratory-methods-food/foods-program-compendium-analytical-laboratory-methods

124 https://www.epa.gov/hw-sw846/sw-846-compendium.

125 https://www.epa.gov/pesticide-analytical-methods/environmental-chemistry-methods-ecm-index-0-9.

126 Article 5(10) When preparing ecodesign requirements, the Commission shall ensure consistency with other Union law and shall: […] (d) take into consideration the protection of confidential business information;

127 https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016L0943.

128 European IP Helpdesk, 2021. Trade Secrets: Managing Confidential Business Information file:///C:/Users/BRACGIU/Downloads/trade%20secrets-EA0921244ENN.pdf.

Regarding the protection of confidential business information and linked to the disclosure on information associated to chemicals, in the context of this method, the provisions in **Article 119 of REACH** could provide some indication on how to assess confidentiality claims. REACH Article 119(1) defines which information from a REACH registration dossier for a substance must always be made publicly available on the ECHA Chemical Database website, whereas REACH Article 119(2) lists information that, subject to justification, may be claimed as confidential. In addition to REACH Article 119, Article 24 of CLP allows the manufacturer, importer or downstream user of a substance/mixture to request the use of an alternative chemical name that refers to that/those substance(s) in a mixture, either by means of a name that identifies the most important functional chemical groups or by means of an alternative designation. Nevertheless, this option is precluded in those cases where the substance is subject to occupational exposure limits or where it is classified exclusively as one or more of the hazardous categories set out under sub-paragraph (III) of point 1.4.1 of Part 1 of Annex I to CLP[129].

Further guidance on this matter, as applicable to REACH and CLP, may be found in the ECHA document "Dissemination and Confidentiality under the REACH Regulation"[130] and "Introductory Guidance on CLP Regulation"[131]. This ECHA guidance should be taken into consideration in assessing possible exemptions from ESPR information requirements for substances. The above-mentioned documents also advise on how to derive a public name for a substance for which confidentiality is requested concerning the IUPAC name, in accordance with Article 10(a)(xi) of the REACH Regulation. With specific regard to substances of very high concern, additional guidance from ECHA on how to protect CBI is available in "Dissemination and confidentiality in the SCIP[132].

Moreover, when the PS team assesses possible exemptions to ESPR information requirements for SoCs based on operator claims related to the need to protect CBI, there are three main recommendations based on the ECHA guidance document "How to protect your confidential business information[133]". These recommendations advise to ensure that: (1) the information to protect is not already public; (2) the confidentiality claim covers fully the desired information; and (3) justification is given to support such an exemption.

Overall, when defining exemptions on information requirements for SoCs based on a CBI request, it is recommended that the PS team takes into consideration the already-existing European regulatory framework that, on the one hand strives to guarantee the right of economic operators to protect trade secrets, and on the other seeks to ensure access to information by the general public and authorities so as to adequately manage the SoCs (a), (b), (c). It should be noted that the ESPR enlarges the information requirements to additionally cover substances that hinder reuse and recycling (SoC (d)). For such substances, allowing any exemption on the grounds of CBI should not

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129 Acute toxicity, Category 4;; Specific target organ toxicity — Single exposure, Category 2 or 3; Specific target organ toxicity — Repeated exposure, Category 2; Hazardous to the aquatic environment — Chronic, Category 3 or 4. Note reference to hazard classes which are not relevant to the identification of substances as SoC (b) according to Article 2(27) have been omitted from this iits.

130 ECHA, 2024. https://echa.europa.eu/documents/10162/1804633/manual_dissemination_en.pdf

131 ECHA, 2019. Introductory Guidance on the CLP Regulation. Version 3.0 https://echa.europa.eu/documents/10162/2324906/clp_introductory_en.pdf/b65a97b4-8ef7-4599-b122-7575f6956027?t=1547546145023

132 ECHA, 2021. Dissemination and confidentiality in the SCIP Database. Version 2.0. https://echa.europa.eu/documents/10162/28213971/dissemination_confidentiality_scip_en.pdf/e0efbea1-d8ec-b67c-de8f-1838b480db6d

133 ECHA, 2028. How to protect your confidential business information, available at: https://www.echa.europa.eu/documents/10162/23221373/example_how_to_protect_cbi_en.pdf/5f2a0b7e-c80f-cb2a-1045-42b0049df793

be contrary to the objective of enhancing the material's circularity, i.e., explicitly allowing the identification of SoC (d) content by waste operators.

It is worth noting that, in principle, the ESPR text does not exclude the possibility to define exemptions only with respect to part of the information that is covered by ecodesign information requirements on the tracking of SoCs. This consideration could open the possibility to, for example, exempt the chemical name of the substance of concern from appearing in the mandatory information requirement on tracking, should the chemical name of the substance not be disclosed for justified reasons of protecting business interests. Where this might be allowed, the obligation by manufacturers/ producers/ supply chain actors to provide all other information elements listed under Art. 7(5) remains.

An exemption from providing the chemical name and identifiers of a substance, if deemed necessary by stakeholders and proposed in the Preparatory Study, could potentially be inspired by the exception envisaged under CLP for certain substances in mixtures, as provided under its Article 24. Under CLP, companies can submit requests to ECHA to use an alternative chemical name which refers to substance with a harmonised classification present in a mixture, if disclosing their full name puts the confidential nature of their business, in particular intellectual property rights, at risk. According to CLP, ECHA has the mandate to approve or not such requests following the criteria reported in Section 1.4.1 of Annex I to CLP, as well as to decide an alternative chemical name either by means of a name that identifies the most important functional chemical groups or by means of an alternative designation. In all cases the names chosen must provide enough information to ensure that the mixture(s) can be handled without risk and that necessary health and safety precautions can be taken in the workplace.

Further guidance on assigning alternative chemical names under CLP can be found in the ECHA guidance on "How to prepare a request for use of an alternative chemical name for a substance in a mixture"[134] and in the associated Lexicon guide[135]. The reference to the CLP process and criteria is here provided solely for reference, in the event that exemptions involving the possibility to use an alternative chemical name were to be defined. However, it should be noted that, contrary to what is provided under the CLP Regulation, the ESPR Regulation does not explicitly envisage a specific procedure for the request, review or granting of exemptions based on the use of an alternative chemical name.

Other duly justified cases for exemption from information requirements

The other cases mentioned below regarding the granting of possible exemptions are not specified in the legal text. Possible additional considerations to take into account when proposing exemptions from information requirements for specific SoCs in the draft proposals for a delegated act could include:

- *Similar exemptions, where present, in other ESPR delegated acts* - Considerations on the exemption for information requirements identified in other Preparatory Studies for other product groups, where the latter present similar life cycle stages and/or function to the product under analysis.
- *Disproportionate costs and administrative burden* – considerations on the economic feasibility, especially for SMEs, of implementing information requirements for specific SoCs. This information will generally be substance- and product-specific and will most

[134] https://echa.europa.eu/documents/10162/1804633/manual_alt_name_request_en.pdf/4bfcbe6a-0025-4305-b848-2bb193cc2a41

[135] Annex VI, Part B to the Dangerous Preparations Directive (Directive 1999/45/EC concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations). Available at: https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:1999L0045:20090120:en:PDF

likely be available only to specific actors in the value chain. To the extent possible, this information should on a preliminary basis be identified during the Preparatory Study in order to evaluate whether there are sufficient grounds to propose such exemptions. These aspects should be further analysed in the Impact Assessment supporting the adoption of ESPR DAs, where broader considerations, associated to the feasibility and proportionality of tracking SoCs or groups of SoCs for a given sector or product group may be analysed (see also section above on technical feasibility).

In terms of the methodological steps to be followed by the PS study team, it is suggested that ***a priori*, no substance-specific exemptions are proposed in the early stages of the PS preparation.** The PS study should encourage stakeholders to provide detailed justifications for the need of any possible exemption, during the stakeholder consultation process supporting the preparation of a Preparatory Study.

In a broader approach towards exemptions to information requirements on tracking, based on the assessment of the availability of sector-specific supply chain information, and other relevant factors, different scenarios could be considered with a progressive approach, for subsequent analysis in the impact assessment phase:

— **Scenario 1** → all SoCs identified under Article 2(27) should be tracked and substance-specific exemptions could only be considered if justified according to Article 7(6)(b) of the ESPR (further explanations in the above paragraphs).

— **Scenario 2** → targeted exemptions for entire substance families, defined e.g. by their structure, function or corresponding hazard classes /hazard categories under Article 2(27)(b) could be considered, if justified. In principle this is only possible if the criteria set out in Article 7(6)(b) are met for the group of substances as a whole, i.e. if such an exclusion is duly justified, based on the technical feasibility, relevance, existence of analytical detection methods, or creating disproportionate burden to companies. As a possible example, this approach could potentially be justified for new hazard classes (such as endocrine disruption for human health categories 1 and 2; endocrine disruption for the environment categories 1 and 2; persistent, mobile and toxic or very persistent, very mobile properties; persistent, bioaccumulative and toxic or very persistent, very bioaccumulative properties) which are currently not recognised by the Globally Harmonised System of Classification and Labelling of Chemicals (GHS) and for which currently obtaining such information from SDSs available in third countries, that do not follow EU legislation, may not be possible.

— **Scenario 3** → progressive approach to exemptions based on broad substance groups, if that could be justified, due to for instance, technical feasibility or proportionality considerations.

Once the aspects above have been investigated, the PS team should draw up a full list of the substances of concern for which specific exemptions might be proposed, together with the reasons for proposing such exemptions. Such a list, by definition, cannot include substances of SoC type (a), as prescribed by the ESPR **Article 7(6)(b)**, as mentioned above. In all the above scenarios, an alternative to the above exemptions could be the introduction of delayed dates of entry into application of the requirements (see also section on deadlines for entry into application below).

Article 7(7) requirement – provision of information beyond the Digital Product Passport

Article 7(7) of the ESPR requires that ESPR delegated acts provide indications on whether information requirements have to be communicated by other means, e.g., beyond the DPP. Such other means to provide information might include the following:

(a) on the product itself;

(b) on the product's packaging;

(c) on a label referred to in Article 16;

(d) in a user manual or other documentation accompanying the product;

(e) on a free access website or application.

Including the additional information on the product itself or on the product's packaging may be challenging due to space constraints that manufacturers may encounter when designing the product and the packaging. Moreover, information on SoCs in the product or packaging could, particularly for mixtures, introduce confusion given the overlap with CLP labelling requirements.

Article 7(7) of the ESPR indicates that "where a digital product passport is available, the required information shall be provided therein". Considering that, pursuant to ESPR Article 7(2)(a) on information requirements for products, these must include "requirements related to substances of concern set out in paragraph 5", the required information on SoCs should always be included in the DPP. Given that Article 7(3) states that "information requirements based on the product parameter set out in Annex I, point (f), shall not concern the labelling of substances or mixtures for reasons relating primarily to their hazards to health or the environment", and considering that most SoCs are likely to be identified due to their hazardous nature regarding human health and the environment, information provided in the DPP should not duplicate or substitute the labelling requirements under the CLP Regulation. Note that this only holds where the CLP labelling provisions apply to a chemical product (either a substance or a mixture), or an intermediate material.

Article 9(4)b of the ESPR indicates that where "other Union law includes a system for the digital provision of information related to a product group which the Commission considers achieves the [relevant] objectives", the Commission may exempt product groups from the requirement to have a digital product passport. This is likely to be the case for a number of energy related product groups which are listed in the EPREL database (European Product Registry for Energy Labelling)[136]. In those cases, the Preparatory Study team is advised to analyse whether and how information requirements on SoCs can be reflected in the EPREL database.

Additional requirements may solely be introduced potentially in a user manual, or via a free access website, when it is relevant from the point of view of the user to have additional guidelines, such as safe use or disposal, due to the existence of SoCs in the product. Such information has previously been requested, for instance, in EU Ecolabel products such as absorbent hygiene products or reusable menstrual cups. In these examples, the information on the use and on the disposal of the product and of the packaging should be provided by means of a printed and/or digital leaflet (note that it has to date not been requested for substances). It is proposed that a similar approach be analysed by the PS team for specific cases related to SoCs.

Deadlines for entry into application

Unless duly justified, the minimum deadline for entry into application of provision in ESPR delegated acts is set in Article 4(4) of the ESPR at 18 months from the date of entry into force of the measure (which is generally 20 days following publication in the OJEU). This general provision applies to all elements in the delegated act.

More specifically, as regards the entry into application of information requirements for substances, Article 7(6)(a) requires the Commission to, as relevant, "lay down dates of application of such information requirements referred to in the first subparagraph of paragraph 5, differentiating between substances of concern where necessary". Consequently, although the default requirement under the ESPR requires the provision of information on SoCs after 18 months, post entry into force,

[136] COMMISSION IMPLEMENTING REGULATION (EU) 2024/994 of 2 April 2024 laying down operational details of the product database established under Regulation (EU) 2017/1369 of the European Parliament and of the Council https://eur-lex.europa.eu/eli/reg_impl/2024/994/oj#:~:text=on%20the%20market.-,Article%C2%A014,-Facilitating%20access%20to

the date of application of this obligation may, with due justification, be delayed in time or, for instance be staggered in time for different SoCs or groups of SoCs.

It is envisaged that any deviation from the default approach (that information on SoCs is provided via the DPP on the general date of entry into application of the delegated act), could be proposed as a result of specific feedback received from stakeholders during the several rounds of stakeholder consultation. These consultations constitute an essential element of the development of the Preparatory Study and the progressive gathering of pertinent information, this evidence to be further supplemented and evaluated in the regulatory impact assessment to accompany the product-specific draft delegated act. Potential categories of SoCs for which delayed/ progressively staged date(s) of application could be proposed include:

- Substances present in the product vs process chemicals not present in the product
- Intentionally added / present substances vs non-intentionally added substances
- Instances based on likelihood / relevance of certain families of substances, in turn based on chemical nature or function (e.g. plasticisers, flame retardants, aromatic amines, phthalates, poly- or per-fluorinated substances, etc).

In making proposals for a staggered or tiered approach to the entry into application of information requirements for SoCs, the following related considerations may also be relevant:

- Entry into force of information requirements coming from other relevant legislations, for example when a SVHC is included into the REACH Candidate List, harmonised classification in the relevant CLP hazard classes or is identified as a POP;
- Deadlines for information requirements identified in other Preparatory Studies for other product groups, where the latter present similar life cycle stages and function to the one under consideration;
- The nature of the sector, in particular considering feedback from stakeholders, on the level of development and implementation of information technologies along the supply chain, (e.g. sector platforms for collecting and exchanging information) and evidence supporting such feedback.

It should be noted that, as already indicated, it is relevant that the Preparatory Study team flags relevant substances which may be in the regulatory “pipeline”, for instance substances under consideration for SVHC identification, POPs under consideration for listing under the Stockholm Convention or substances in the registry of intentions of ECHA for harmonised classification and labelling. These substances are potential future SoCs which may only obtain such consideration following the adoption of the delegated act for the product analysed in the Preparatory Study. The technical, practical and legal consequences of specific substances becoming SoCs following adoption of a delegated act will have to be taken into consideration during the preparation of the delegated act, given that if it is assumed that a dynamic link exists between for instance, new harmonised classification, and the triggering of the information requirements under the ESPR, it may not be possible to assess and address potential exemptions, if these were to be justified.

Review of the list of substances and SoCs under Article 2(27)

Given the rapidly changing and evolving landscape in terms of technologies and chemicals used in the manufacture of products, the identification of SoCs under Article 2(27) and in particular under point (d) for a given product may change over time. Consequently, in the development of the Preparatory Study supporting the corresponding product-specific delegated act under the ESPR, consideration could be given to the appropriateness to take account of these aspects in proposing the content already to be scrutinised, together with a date for the review of the delegated act. With regard to anticipated technical progress, and/ or enhanced chemical detection techniques over time, a time-delayed tier of application within the delegated act could be proposed (i.e., rather than waiting for the future revision), but with greater ambition, anticipating lower (i.e. stricter) limiting thresholds, e.g., for the first point on “emerging or improved recycling technologies”, or the last point on ‘new evidence’ mentioned below.

Concerning the content and date of the review of the delegated act, the following could be considered, with regard to chemical substances, also subject to the findings of the future accompanying regulatory impact assessment on a product-by-product basis (or for a horizontal discrete ecodesign measure):

- **Emerging or improved recycling technologies** able to overcome some of the identified recycling issues,
- **New legislative measures on products** posing restrictions on substances for safety reasons, that could create new barriers to recycling,
- **New substances** on the market that could improve the durability and quality of the product, potentially overcoming all or some of the quality issues,
- **New potential applications** of secondary materials (providing 1-to-1 substitution of primary material or in lower value applications),
- **New evidence** of substances which have proven to be disruptive for recycling/reuse.

Technological developments as well as the new potential markets and applications for relevant recycled materials and reused products should be monitored, e.g., by maintaining contacts with producers and recyclers and considering other sources of data, including EU-wide umbrella associations that provide specific and cross-sectoral expertise on a broad range of materials.

The review period of any delegated act will have to be discussed ad-hoc, taking into account the practicalities discussed by the responsible DGs of the European Commission. While any ESPR product DA review would require a new delegated act, the new delegated act would also be preceded by some form of supporting study in the form of a Preparatory Study and potentially (usually) an Impact Assessment, as included in the whole decision-making process (please refer to Chapter 2 in Section A for further information on how the development of ecodesign measures takes place). These practical and regulatory constraints should be discussed during the drafting of the draft proposals for a new or revised delegated act.

4.4 Summary of Section B

The information on substances identified up to this moment (**SoCs under Art. 2(27)**) constitute the **Bill of Substances of Concern (Bill of SoCs)**, representing the list of substances that are subject to information requirements to enable their tracking along the value chain. According to the definition of value chain (Article 2(11)), the Bill of SoCs includes SoCs which:

- remain in the product;
- are included in the post-consumer waste;
- are included in the final recyclate after the end-of-life treatment of the post-consumer waste;
- are present along the life cycle of the product (as input and output flows, e.g. emissions, to each life cycle stage, included end-of-life scenarios, including those that do not remain in the product).

Table 6. Details of the general Bill of SoCs built in Preparatory Studies.

SoCs Art. 2(27) (a)	SoCs Art. 2(27) (b)	SoCs Art. 2(27) (c)	SoCs Art. 2(27) (d)										
			Existing regulatory and customer-driven limitations					Technical constraints					
								Process disturbing			Quality disturbing		
Name[137] and function	Name and function	Name and function	Name and function	Sector of application	Reference policy	Thresholds for tracking[138] based on restriction c relevant regulations and customer limits c_{alert} (%w/w)*	Origin (process stage)	Name and function	Thresholds for tracking c_{alert} (%w/w)	Origin (process stage)	Name and function	Thresholds for tracking c_{alert} (%w/w)	Origin (process stage)
…	…	…	…					…			…		
…	…	…	…					…			…		

Source: JRC's own elaboration.

*As defined in Section B3.

137 According to the ESPR Article 7(5) (a).

138 If applicable, depending on the approach adopted of those proposed in the method.

Table 5 included in Section B2 contains the elements to be listed in the “Bill of SoCs” (see also a possible simplification in **Table 5 – B**). In this line of argument, **Table 6** should be used to extract the information concerning SoCs. To complement the name and function of the SoC identified, their CLP classification should also be added. To reduce the complexity of such table, this information is not included in **Table 6**; however, it should be included when developing the Preparatory Study for the relevant product/product group.

The summary proposals of **Section B** aim to provide guidance for the development of information requirements on substances of concern and performance requirements on substances of concern, in particular with respect to the substances of concern to be tracked and included in the DPP.

The main steps to be carried out involve the completion of **Table 5** (or simplified **Table 5 – B**) and **Table 6**, which are needed to build the tables of identified substances of concern as a further step after the inventory of substances needed to fulfil the method described in the present report.

Table 7. Summary of the method in Task B5 - Section B.

Methodology step	Where?	Required by MEErP?	Any addition in Task B5?
identification of SoCs			
identification of SoCs a, b, c (remaining and not remaining in the product)	Task 5	new (Task B5)	- identify SoCs a, b, c in the product - identify SoCs a, b, c along the cycle of the product - identify location of SoCs a, b, c in the product, component or material - identify location of SoCs a, b, c in the post consumer waste and recyclate - identify SoCs a, b, c in the product and parts in direct contact with the consumer
intentionally added susbtances in the product	Task 5	new (Task B5)	- identify SoCs d in the product - identify SoCs d along the cycle of the product - identify location of SoCs d in the product, component or material - identify location of SoCs a, b, c in the post consumer waste and recyclate - identify SoCs d in the product and parts in direct contact with the consumer
non-intentionally added susbtances in the product	Task 5	new (Task B5)	- identify SoCs d in the product - identify SoCs d along the cycle of the product - identify location of SoCs d in the product, component or material - identify location of SoCs a, b, c in the post consumer waste and recyclate - identify SoCs d in the product and parts in direct contact with the consumer
defining information requirements for SoCs			
information requirements for substances of concern	Task 5	new (Task B5)	the information requirement should include: - a) the name or numerical code of the substances of concern present in the product - b) the location of the substances of concern within the product - c) the concentration, maximum concentration or concentration range of the substances of concern, at the level of the product, its relevant components, or spare parts - d) relevant instructions for the safe use of the product - e) information relevant for disassembly, preparation for reuse, reuse, recycling and the environmentally sound management of the product at the end of its life
thresholds	Task 6	new (Task B5)	- minimum concentration threshold that triggers compliance with information requirements
exemptions	Task 6	new (Task B5)	- identify exemptions of SoCs to track

Source: JRC’s own elaboration.

Note: the distinction between intentionally and non-intentionally added substances applies also to SoCs (a), (b) and (c).

Box 3. Suggested stakeholder engagement during the steps identified in Section B of the method.

→ In the preliminary stakeholder questionnaire, information about substances of concern type (d) (SoC (d)) that could be included in the product and its life cycle should be requested to stakeholders. If possible, data regarding concentration of substances should also be sought. This should be carried out during Task 0 of the MEErP.

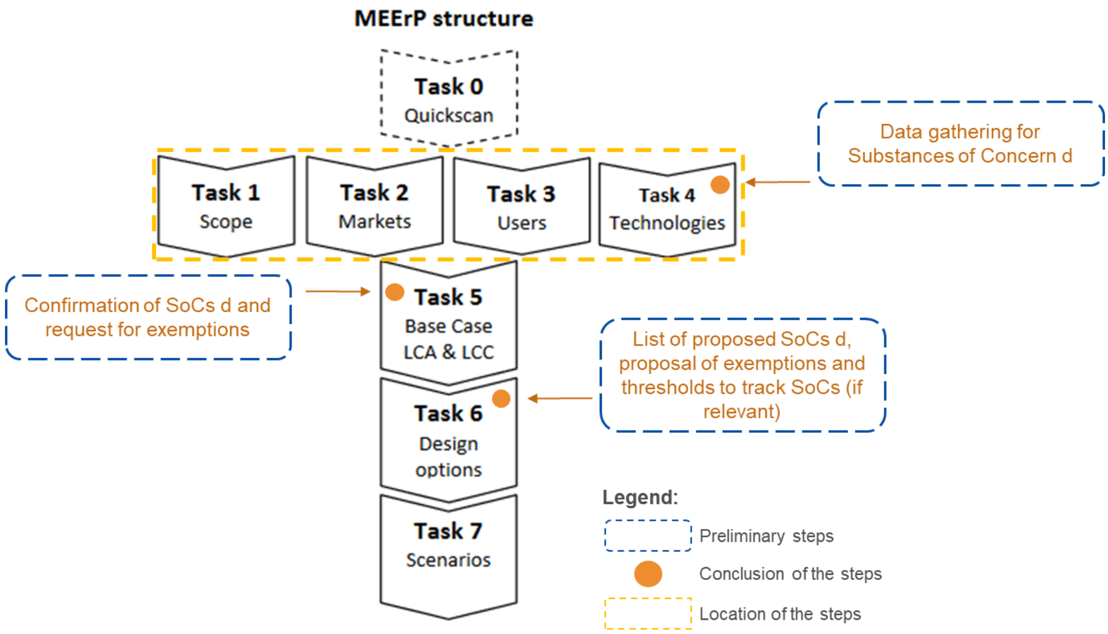
→ In the first stakeholder meeting, where the work on Task 1 of the MEErP and preliminary work on Tasks 2-4 is discussed, the same request above complemented with the request of possible exemptions should be made again to stakeholders. Possible exemptions to SoCs requirements should be requested using a "form" prepared by the PS team, to be made available to stakeholders, who should then submit the information requested. The PS team should gather and analyse the exemption requests received (please find a proposal of a questionnaire to stakeholders in Annex V).

→ In the second stakeholder meeting, where the work on Tasks 2-4 of the MEErP is discussed, the PS team should present the evidence gathered on substances of concern type (d) (SoC (d)) that could be included in the product and over the life cycle. Stakeholders are expected either to confirm or to provide further information on the evidence presented during and after the meeting, in relation to candidate substance for consideration as SoCs (d), and any possible exemptions. The exemption form should also be made available again (Annex V).

→ In the third/final stakeholder meeting, where the work on Tasks 5-7 of the MEErP is discussed, the PS team should present: (i) the proposal for SoCs (d), (ii) the proposal for exemptions and (iii) the thresholds for tracking SoCs (if relevant). The PS team should seek input from stakeholders to confirm or to provide further information.

→ In addition, sub-groups with relevant stakeholders could be organised at any moment during the development of the Preparatory Study, as needed. Similarly, specific surveys could be developed and shared with relevant stakeholders for the request of information on substances.

Figure 7. Overview of the steps in Section B of Task B5 within the MEErP.



Source: JRC's own elaboration adapted from COWI and VHK, 2011.

5 Section C: Method for developing performance requirements on substances

This section proposes a method to develop performance requirements on substances occurring over the life cycle of products.

The basis for this method is Article 6 of the ESPR 'Performance requirements', which states the following:

"*1. Products shall comply with performance requirements related to the* ***product aspects*** *as laid down in the delegated acts adopted pursuant to Article 4.*

2. The performance requirements shall be based on the relevant ***product parameters*** *referred to in Annex I and shall, as appropriate, include either or both of the following:*

> *(a) minimum or maximum levels in relation to a specific product parameter or a combination thereof;*
>
> *(b) non-quantitative requirements that aim to improve performance in relation to one or more of such product parameters.*"

Annex I to the ESPR lists 20 different product parameters addressing the product aspects laid down in Article 5, ranging from the *durability* and *reliability* of the product or its components, to the *ease of repair* and *maintenance*, and *design for recycling*, but also the *environmental*, *carbon* and *material footprint* of the product. The method presented in this Section C **focuses only on product parameter f) of Annex I**, which refers to the *"use of substances, and in particular the use of substances of concern, on their own, as constituents of substances or in mixtures, during the production process of products, or leading to their presence in products, including once these products become waste, and their impacts on human health and the environment*". How to set performance requirements on product parameters other than point (f) in Annex I is out of the scope of this report and is addressed in other tasks (i.e., Task B2, etc.) of the ESPR methodology.

The methodology described in Section C requires the undertaking of a literature review, requesting and appraising stakeholder feedback, taken together with the **work already developed in Sections A and B**. Particularly, the work in **Section A** is to be used for the **life cycle assessment** in relation to specific substances used within the product lifecycle which may have a relevant impact on the environmental performance of the Base Case. In addition, once the **identification of SoCs** as defined in Art. 2(27) is finalised as part of **Section B, potential performance requirements** may be developed regarding such SoCs, particularly where related to any of the product aspects listed in Article 5.

With respect to **product parameter (f) of Annex I, Art. 6(3)** states that "*Performance requirements based on the product parameter referred to in Annex I, point (f), shall not restrict, for reasons relating primarily to chemical safety, the presence of substances in products. However, the setting of performance requirements shall also, where appropriate, reduce significant risks to human health or the environment*".

When setting performance requirements, it is important to consider **Art. 5(11)** of the ESPR, which states the criteria that ecodesign (performance and information) requirements shall adhere to the following constraints:

> *"(a) there shall be no significant negative impact on the functionality of the product, from the perspective of the user;*
>
> *(b) there shall be no adverse effect on the health and safety of persons;*
>
> *(c) there shall be no significant negative impact on consumers in terms of the affordability of relevant products, also taking into account access to second-hand products, durability and the life cycle cost of products;*

(d) there shall be no disproportionate negative impact on the competitiveness of economic operators and other actors in the value chain, including SMEs, in particular microenterprises;

(e) there shall be no proprietary technology imposed on manufacturers or other actors in the value chain;

(f) there shall be no disproportionate administrative burden on manufacturers or other actors in the value chain, including SMEs, in particular microenterprises."

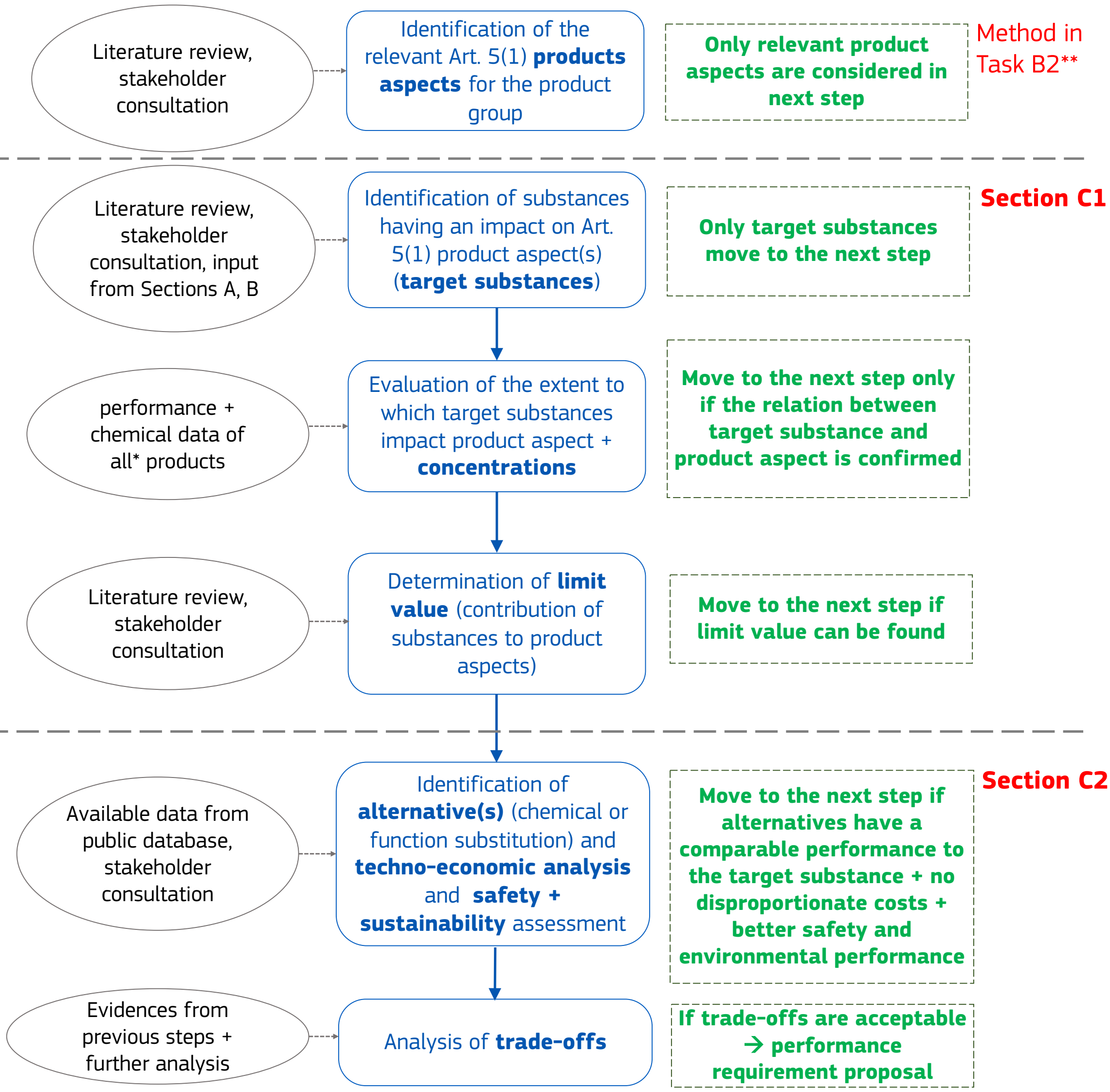
Annex II to the ESPR outlines the procedure to follow for the setting of performance requirements. Annex II envisages a technical, environmental and economic analysis, and moreover states the following with respect to performance requirements on substances: "*Any concentration limit for substances as referred to in Annex I, point (f), shall be based on a thorough analysis of the sustainability of the substances and their identified alternatives, and shall not have significant adverse effects on human health or the environment. Any performance requirement concerning substances as referred to in Annex I, point (f), shall take into consideration existing chemical safety assessments performed by the relevant Union bodies for the substances concerned, as well as safe and sustainable by design criteria for chemicals and materials developed by the Commission*[139]*. Proposed concentration limits shall also consider aspects of enforceability, such as analytical detection limits*".

The next sections take into account all the ESPR aspects mentioned above. In particular, **Section C1** addresses a method for developing performance requirements for substances, while **Section C2** shows a preliminary evaluation of alternatives for substances, to determine whether suitable alternatives are available; this is in order to assess and prevent any regrettable substitution taking place, where it might be derived as a direct or indirect effect of establishing performance requirements on substances (see **Figure 8**).

The method outlined in the following sections should be carried out as part of **Task 5 "Environment and Economics"** and **Task 6 "Design options"** of the MEErP.

[139] In 2022 the Joint Research Centre (European Commission) developed a framework for assessing safe and sustainable by design chemicals and materials. At the time of writing this report (June 2025), the Commission had not yet developed any safe and sustainable by design criteria.

Figure 8. Method for developing performance requirements on substances.



* All products for which data can be retrieved, not only Base Case and/or pseudo-worst-case approach.
** Task B2 'Method for the assessment of circularity aspects and integration in or relation with the Method for the Ecodesign of Energy-related Products (MEErP)'.

Source: JRC's own elaboration.

5.1 C1: Determining the impact of substances in products on Article 5(1) product aspects

Performance requirements on the presence of substances in products and/or in their life cycle have the aim of improving one or more of the **product aspects mentioned in Art. 5(1)** of the ESPR. Given the complexity of the interaction of different product aspects, designing performance requirements can be a challenging task. Section C1 proposes a structured approach to evaluate the need for performance requirements, and the method by which to set them.

Performance requirements could take the form of specific restrictions, limitations or conditions of use, on substances, considering the product aspects in Art. 5(1). Hereafter, a substance which is a candidate for a performance requirement will be referred to as the **target substance**.

Whilst **restrictions** often take the form of mandatory limitations on the concentration in which a substance is allowed to be present in a certain product or component, there are other means of restricting substances. "**Conditions of use"** can generally be seen as specific requirements on how a substance is to be used (e.g. required use of certain personal protective equipment, avoidance of certain conditions of use, mandatory use or implementation of local exhaust ventilation, etc). An example of a condition of use is given in the BREF for Textiles for the bleaching of fibres with hydrogen peroxide (H_2O_2): "*to achieve good results and avoid damage to the fibre when removing starch-like size, it is essential to add hydrogen peroxide at pH > 13. These operating conditions minimise OH* radicals, which are responsible for cellulose damage*" [140].

As mentioned in Section A, substances having a specific function are used in products in order to convey a specific property. The use of a specific substance for a specific function may affect directly or indirectly one or more of the product aspects in Art. 5(1), thus the inventory of collected substances in Section A may be used as input for this section work. For example, UV absorbers and stabilisers are added to plastic products to absorb the high energy of ultraviolet light and to protect the plastic product from degradation due to this radiation, which may otherwise affect the technical lifetime of the product (e.g., as added to PVC in window frames). Another example is the curing step in the manufacturing of silicone rubber, which uses a catalyst, e.g. platinum, to convert silicone rubber from a highly adhesive gel or liquid into a solid[141]. In the absence of suitable alternatives, limiting the presence of substances with specific functions may affect the overall functionality of the product. Therefore, it is important that Art. 5(11)(a) of the ESPR is duly taken into account, i.e. that the restriction of substances does not translate into a *"significant negative impact on the functionality of the product, from the perspective of the user".*

Article 5(1) of the ESPR lists 16 product aspects that address the environmental impacts of products:

"*(a) durability;*

(b) reliability;

(c) reusability;

(d) upgradability;

(e) repairability;

(f) the possibility of maintenance and refurbishment;

(g) the presence of substances of concern;

(h) energy use and energy efficiency;

(i) water use and water efficiency;

(j) resource use and resource efficiency;

(k) recycled content;

(l) the possibility of remanufacturing;

(m) recyclability;

(n) the possibility of the recovery of materials;

(o) environmental impacts, including carbon footprint and environmental footprint;

(p) expected generation of waste".

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140 Starch is used as a "sizing agent" (a step in woven textile production). After the "sizing", also a desizing process is needed and this desizing is a kind of bleaching process where H_2O_2 can be used. Reference: Textiles BREF https://eippcb.jrc.ec.europa.eu/reference/textiles-industry

141 https://www.yhlsr-silicone.com/blog/how-is-silicone-produced/, https://www.sciencedirect.com/science/article/pii/S0300944018300730

The use of a given substance may affect negatively one or more of the above-mentioned product aspects. The PS team should therefore investigate any link(s) between the use of substances and the aspects above. To facilitate the task, it is proposed to break down the analysis of the product aspects in Art. 5(1) linking them to the grouping made in Annex I to the ESPR. In this way, some product aspects will be analysed in combination and/or taking into account the product parameters cited in Annex I, as explained in the next section.

The PS team is thus recommended to explore the existence of any **relationship** between the use or presence of one or several substances and one or several product aspects, including any synergistic or antagonistic effects that may occur. Wherever possible, the PS team should describe them, at least in a qualitative manner; this could be further investigated using the product parameters included in Annex I ESPR. Potentially, such assessments may be available to the industries concerned in the context of a specific product development which takes into account ecodesign aspects. However, such assessments go well-beyond the reasonable scope of work that can be carried-out in an ecodesign preparatory study, and might only be included if, at the time of the preparation of the Preparatory Study, clear and published results on these matters have been obtained via stakeholders from e.g. industry, academia, and/or other research organisations and expert stakeholders. **Table 8** below serves to illustrate how the products aspects in Art. 5(1) are linked to the product parameters in Annex I.

Table 8. Links between products aspects in Article 5(1) and product parameters in Annex I.

Product aspects in Art. 5(1)	Product parameters in Annex I
(a) durability and (b) reliability	(a) durability and reliability; (s) functional performance and conditions for use, including as expressed through the ability to perform its intended use, precautions for use, skills required and compatibility with other products or systems
(c) reusability; (d) upgradability; (e) repairability; (f) the possibility of maintenance and refurbishment; (l) the possibility of remanufacturing; (m) recyclability; (n) the possibility of the recovery of materials;	(b) ease of repair and maintenance; (c) ease of upgrading, reuse, remanufacturing and refurbishment; (d) design for recycling; (e) avoidance of technical solutions detrimental to reuse, upgrading, repair, maintenance, refurbishment, remanufacturing and recycling of products and components; (k) incorporation of used components; (l) quantity, characteristics and availability of consumables needed for proper use and maintenance; (t) lightweight design
(h) energy use and energy efficiency; (i) water use and water efficiency; (j) resource use and resource efficiency	(g) use or consumption of energy, water and other resources in one or more life cycle stages of the product, including the effect of physical factors or software and firmware updates on product efficiency and including the impact on deforestation; (j) weight and volume of the product and its packaging, and the product-to-packaging ratio; (t) lightweight design
(k) recycled content; (m) recyclability; (n) the possibility of the recovery of materials;	(h) use or content of recycled materials and recovery of materials, including critical raw materials
(o) environmental impacts, including carbon footprint and environmental footprint;	(m) the environmental footprint of the product, expressed as a quantification, in accordance with the applicable delegated act, of a product's life cycle environmental impacts, whether in relation to one or more environmental impact categories or an aggregated set of impact categories; (n) the carbon footprint of the product; (o) the material footprint of the product; (p) microplastic and nanoplastic release as expressed through the release during relevant product life cycle stages, including manufacturing, transport, use and end-of-life stages; (q) emissions to air, water or soil released in one or more lifecycle stages of the product as expressed through quantities and nature of emissions, including noise

Product aspects in Art. 5(1)	Product parameters in Annex I
(p) expected generation of waste	(r) amounts of waste generated, including plastic waste and packaging waste and their ease of reuse, and amounts of hazardous waste generated; (t) lightweight design

Source: JRC's own elaboration.

Many of the product aspects listed in Article 5(1) are closely linked to the concept of making products suitable for a circular economy based on **reuse and recycling**, i.e. *reusability, upgradability, repairability, possibility of maintenance and refurbishment, recycled content, possibility of remanufacturing, recyclability, and possibility of the recovery of materials*.

Other aspects such as durability and reliability are related to the **performance or fitness for use** of the products, while resource, energy and water use and resource, energy and water efficiency should be referred to in **all stages of the life cycle** of the products.

For the analysis of these aspects, the PS team will have to investigate if the presence of specific substances can play a negative role on one or more of the life cycle stages. The main sources of information will be via **literature review and targeted consultation** means, especially since the topic of substances hindering circularity is quite novel in product policy and may depend not only on the product where the substance is used, but also on the applications for the reused, upgraded, repaired, or refurbished product, for which detailed knowledge may not always be available to the PS team.

In the context of each Preparatory Study, the most relevant product aspects, which are specific to the product group concerned, will be determined in order to narrow down the scope and extent of the assessment to those elements that are most pertinent. When assessing the impacts of relevant substances, the PS study team should concentrate on their relationship with the above-mentioned Art. 5(1) relevant product aspects. Relevant product aspects can be identified by applying the method described in the separate ESPR Methodology document (Task B2): 'Method for the assessment of circularity aspects and integration in or relation with the Methodology for the Ecodesign of Energy-related Products (MEErP)'[142].

Relevant product aspects for a specific product group should be analysed from the point of view of the interactions between each product aspect and substances, as explained in the next section. It should be noted that the method developed under **Task B2** considers product aspects contained in the ESPR text: **g) "*the presence of substances of concern*"** and **o) "*environmental impacts, including carbon footprint and environmental footprint*"** as product aspects that are always relevant.

There will be cases where trade-offs will need to be investigated, e.g. substances that convey a higher durability to the product, but which have the effect of decreasing its recyclability, or increase its overall environmental impacts. As a result, for the same product there may be more than one 'optimum' choice in terms of overall sustainability, depending on differences in situation or boundary conditions. This should be further analysed and weighed up by the PS team as part of the Design Options definition and assessment according to MEErP Task 6. A general system of weightings and rules seems difficult to envisage. It is recommended that the PS team deals with these *ad hoc*, taking into account stakeholder engagement through consultations in the Preparatory Study, and policy considerations in the Impact Assessment. Moreover, trade-offs may be easier to

[142] Rodriguez Manotas, J., Gonzalez Torres, M., Magrini, C., Senatore, V., Lodato, C. et al., Method for the assessment of circularity aspects and integration in or relation with the Methodology for the Ecodesign of Energy-related Products (MEErP), Publications Office of the European Union, Luxembourg, 2025, https://data.europa.eu/doi/10.2760/4572606, JRC143212.

analyse depending on the result of the assessment of the interactions between each product aspect and substances, as described in the next section.

5.1.1 Impact of substances on product aspects

This section reports examples of substances affecting the product aspects across sectors. When found, specific concentration values or absolute amounts of substances in the product or along the life cycle should be reported, as well as a quantification of the corresponding effect on the product aspect(s) under investigation.

The analysis of examples may be preparatory to the identification of a link among certain substances and the product aspects, as suggested in the section above.

Product aspects: (a) durability and (b) reliability

ESPR defines **durability** as the '*ability of a product to maintain over time its function and performance under specified conditions of use, maintenance and repair',* whereas **reliability** is defined as the '*probability that a product functions as required under given conditions for a given duration without an occurrence which results in a primary or secondary function of the product no longer being delivered*'.

According to Annex I to the ESPR, (a) **durability and reliability of the product or its components** are *'expressed through the product's guaranteed lifetime, technical lifetime, mean time between failures, indication of real use information on the product, resistance to stresses or ageing mechanisms'*; the link between these parameters and substances should be investigated when setting performance requirements.

The PS team should investigate how the performance of the products included in the scope of the product group is measured by means of performance tests or fitness for use analyses. It should be noted that they should also investigate if the performance and durability of the products is negatively affected by certain substances: (i) included in the chemical composition of the products (remaining in the product); (ii) used along the life cycle of the product (not necessarily remaining in the product); and (iii) even not intentionally added, but still affecting the performance and thus the durability of the products (to the extent that this can be determined).

For example, a certain mix of fibres in apparel textiles may have been used with the aim of increasing the durability of the products. However, this could later hinder the recycling of the products due to the inherent nature of the mix of fibres used, where they are difficult to separate. Examples include the use of elastane (also referred to as Lycra® or spandex) included in tights to improve fit and durability, or the mixing of virgin and recycled wool fibres, which, since they are recycled, have shorter fibre lengths which can in turn decrease the yarn strength[143].

There could also be a substance that is part of a product, for example a battery, which due to ageing is degraded and thus the battery becomes less efficient or even fails totally[144].

As with durability, another possibility is where the presence of a substance hinders the **reliability** of a product in which it is found. The PS team should investigate the possible link between the use of specific substances and reliability; note that such a relationship is likely to be very product specific.

An example of reliability and durability that can be given for paints is the case of fungal resistance for exterior masonry finish and wood paints. This resistance is measured in accordance with PT7 of

[143] Wood, E., Overview of Wool Yarn Manufacture, Woolwise, The Australian Wool Education Trust, 2009, https://www.woolwise.com/wp-content/uploads/2017/07/Wool-482-582-08-T-02.pdf.

[144] M. R. Palacín, A. de Guibert, Science351, 1253292 (2016). DOI: 10.1126/science.1253292. Available here https://www.science.org/doi/epdf/10.1126/science.1253292.

the Biocidal Product Regulation (EU) No 528/2012 (BPR), using standard EN 15457. A certain score should be obtained for these paints, in order to be awarded a specific class of fungal resistance, and this is related to the amount or concentration of PT7 (dry-film[145]) preservatives included under the list of constituents of the paint. Here, it should be noted that the concentration of biocides in products is limited due the characteristics of these chemicals, which are often subject to restrictions under REACH or the BPR. In this case, the PS team should investigate possible trade-offs derived from the use of substances that have an impact on reliability and durability, but that may be restricted for other reasons.

An example of a specific substance hindering the reliability of a product could be where incompatible alloys are juxtaposed (via a poor design), leading to accelerated oxidation or gradual failure of the parts, for instance in nuts and bolts in electrical equipment. Also, a specific substance might be used in a seal on e.g., a washing machine door, thus causing the washing machine to fail at a certain point, or hindering its intended purpose, i.e. by provoking the leak of water. In this case, the seal mechanism should be substituted with an alternative one that enables lifetime extension, if possible. Also, the presence of substances such as copper, bismuth or lead in steel has been found to reduce the hot ductility, temper embrittlement, toughness and weldability of steel, therefore impacting the reliability and durability of final products made of steel[146]. Note that the examples given here are purely illustrative.

The product parameter(s) of Annex I to the ESPR could also be linked to durability and reliability by focusing on substances that might hinder the '*functional performance and conditions for use, including as expressed through the ability to perform its intended use, precautions for use, skills required and compatibility with other products or systems'*, of the product under study including the life cycle of the product.

<u>Product aspects: (c) reusability; (d) upgradability; (e) repairability; (f) the possibility of maintenance and refurbishment; (l) the possibility of remanufacturing; (m) recyclability; (n) the possibility of the recovery of materials</u>

Several product aspects listed in Art. 5(1) are concepts closely related to extending the lifetime of the product, its component(s) and/or the materials used within the product. This group of product aspects addresses the extent to which repair, maintenance, upgrade, refurbishment, remanufacturing, reuse, recycling and recovery occur may be increased by design-related solutions aiming to keep the product and its materials in the material and use loop for longer.

For such product aspects, the main task of the PS team is to research and identify substances that can have a negative effect on the extension of the lifetime of the product. This means, in particular, focusing on substances that may interfere with parameters such as the "*number of materials and components used, use of standard components, use of component and material coding standards for the identification of components and materials, number and complexity of processes and tools needed, ease of non-destructive disassembly and re-assembly, conditions for access to product data, conditions for access to or use of hardware and software needed*", as mentioned in Annex I to the EPSR for all product aspects mentioned above. It should be noted that these parameters may have the potential to simplify an extended or circular use of a product, its components, and the materials in it, in order to keep them longer for society's use.

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145 Dry-film preservatives are active substances within the meaning of Article 3(1)(c) of Regulation (EU) No 528/2012 that are for use in product-type 7 as described in Annex V to that Regulation, in particular for the preservation of films or coatings by the control of microbial deterioration or algal growth in order to protect the initial properties of the surface of materials or objects.

146 Rod, Becker and Nylen, Opportunities and dangers of using residual elements in steels: a literature survey, Jernkontorets Forskning, 2006. Available at: https://www.jernkontoret.se/globalassets/publicerat/forskning/d-rapporter/d819.pdf.

The identification of substances detrimental to the product parameters mentioned above is expected to be difficult and of somewhat limited extent, since such product parameters are mostly related to the number and combination of materials, rather than substances per se present in them. Nevertheless, there could be substances that, due to their hazardous properties, affect the possibility of non-destructive disassembly, or the number of complexity of processes and the tools needed for such disassembly, by virtue of human and/or environmental exposure to the hazardousness of the substances via e.g. leaching, dust generation or spillage, which should be avoided. An example related to disassembly and re-assembly is when removal or substitution of batteries take place. Another example could be related to the presence of adhesives that impede the non-destructive disassembly of the product and substitution of broken parts, such as the use of adhesives that impede re-assembly of footwear because if the sole is removed, the upper material would be destroyed in the process of removing the worn-out soles[147], thus impeding the full repair potential of the shoe. Moreover, soles assembled with adhesives are mostly manufactured using moulds that are proprietary to specific footwear brands or even models. The latter considerations, however, do not specifically apply in principle to substances, but rather refer to the general difficulties experienced in repairing footwear.

For the product aspects repairability and possibility of maintenance, the PS team will also have to investigate how substances can affect the "*characteristics, availability, delivery time and affordability of spare parts, modularity, compatibility with commonly available tools and spare parts, availability of repair and maintenance instructions*" (as mentioned in Annex I, point b). **Repair** is defined in the ESPR as 'one or more actions carried out to return a defective product or waste to a condition where it fulfils its intended purpose'[148]; while **maintenance** is defined as 'one or more actions carried out to keep a product in a condition where it is able to fulfil its intended purpose'. An example of substances affecting the possibility of repair can be the use of polymeric materials that cannot be disassembled – but instead only broken apart – and thus not substitutable. Examples of substances potentially limiting maintenance could be related to the presence of dyes that discolour during the use stage of the product, such as dyes in clothes that fade when washed at normal (30-40°C) temperatures, thus impeding the proper maintenance of the product by the (non-specialised) user.

For the product aspects addressing upgradability, the possibility of refurbishment and the possibility of remanufacturing, key parameters are modularity (the product is built from individually distinct functional units), transformability, detachable elements, adjustable sizing, and customisable surfaces, so that the product is easier to be transformed into another product used for slightly different purposes. **Upgrading** is defined in the ESPR as 'actions carried out to enhance the functionality, performance, capacity, safety or aesthetics of a product'; **refurbishment** 'means actions carried out to prepare, clean, test, service and, where necessary, repair a product or a discarded product in order to restore its performance or functionality within the intended use and range of performance originally conceived at the design stage at the time of the placing of the product on the market'; and **remanufacturing** is defined as 'actions through which a new product is produced from objects that are waste, products or components and through which at least one change is made that substantially affects the safety, performance, purpose or type of the product'.

For the above aspects, it is relevant to investigate the effects brought about by SoCs as defined in Art. 2(27)(a) and (c), such as: brominated flame retardants used during the manufacture of fire-resistant plastic products; plasticisers used to improve the flexibility of plastics (of which the most common plasticisers are phthalates); stabilisers used to protect plastic materials from thermal degradation during processing, or use as lead-based (used in pipes, cables in EEE) or cadmium-

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[147] Duven, T., 2023. Let the people repair their shoes! Available here: https://medium.com/@tobiasduven/let-the-people-repair-their-shoes-a94996a96d68.

[148] This definition is in line with the one provided in the standard EN 45554 'General methods for the assessment of the ability to repair, reuse and upgrade energy-related products'.

based (used in building profile) compounds[149]. In all of these cases, the presence of such substances as legacy chemicals in recycled materials (e.g. plastics), and products made from these, is subject to limitations defined in chemicals legislation (i.e. REACH, POPs Regulation, etc.), due to their risks to human health and the environment, and thereby their uptake in new products to be placed on the market should be prevented or at the very least limited. Such cases, when specifically identified in a product by the PS team, should be flagged in the preparatory study. This is relevant even though for such substances, whose main impacts relate to chemical safety, their limitation via performance requirements under the ESPR is in general not possible.

For repairability, upgradability, possibility of refurbishment and possibility of remanufacturing, it may also be important to analyse if any relevant legacy substances occur in products that affect the incorporation of used components derived from them into new or refurbished products, as mentioned in point (k) of Annex I to the ESPR. As indicated in Section B and above, such impacts, if identified, should be flagged in the Preparatory Study; note, however, that this would not be relevant with regard to defining a performance requirement for such substances.

For the product aspects of reusability and recyclability, it is important to focus not only on the substances that can hinder the second life of the product, but also on the substances that can negatively affect the End-of-Life operations related to preparation for reuse and recycling. In addition, the PS team should assess how substances can affect the *"use of easily recyclable materials, safe, easy and non-destructive access to recyclable components and materials, components and materials containing hazardous substances, material composition and homogeneity, possibility for high-purity sorting"*, (as mentioned in Annex I, point d).

Reuse is defined in Art 3(13) of the WFD as '*any operation by which products or components that are not waste are used again for the same purpose for which they were conceived*'. A complementary definition is included in Standard EN 45554 'General methods for the assessment of the ability to repair, reuse and upgrade energy-related products' as the 'process by which a product or its parts, having reached the end of their first use, are used for the same purpose for which they were conceived'. **Recycling** is defined in the Waste Framework Directive (Directive 2008/98/EC) as 'any recovery operation by which waste materials are reprocessed into products, materials or substances whether for the original or other purposes. It includes the reprocessing of organic material but does not include energy recovery and the reprocessing into materials that are to be used as fuels or for backfilling operations.

For both the product aspects **reuse** and **recycling** there may be a direct link not only with Substances of Concern (SoC) as defined under Art. 2(27)(a), (b), and (c), listed for their hazardous properties, but also regarding SoC under Art. 2(27)(d), which were described extensively in Section B1. It might be expected that substances identified as SoCs under Art. 2(27)(d) for information requirements could also be identified as substances possibly eligible for performance requirements (i.e. restrictions) to improve product aspect (m) on recyclability. The PS team will need to evaluate the appropriateness and proportionality of establishing performance requirements for such substances, considering whether: (i) information requirements on SoCs under Art. 2(27) (d) are sufficient to mitigate adverse impacts on recycling, (ii) there is variability in the composition and performance of products on the market (please refer to **section 5.1.2** Proposed approach for setting restriction values in performance requirements); (iii) it is effective and proportional to set such a performance requirement.

One example of substances impacting reusability is related to the degradation of substances included in the product and/or due to the incorporation of substances during the use stage, where these would impede the reuse of the product, for instance, in the formation of lanthionine and/or

[149] Swetlana Wagner, Martin Schlummer, Legacy additives in a circular economy of plastics: Current dilemma, policy analysis, and emerging countermeasures, Resources, Conservation and Recycling, Volume 158, 2020, 104800, ISSN 0921-3449, https://doi.org/10.1016/j.resconrec.2020.104800.

lysinoalanine, results from the bleaching of wool with sodium hypochlorite. Here, the disulphide bonds of the cysteine amino acids of the wool react with the chlorinated compounds, thus resulting in noticeable yellowing and darkening of the wool used in apparel, which possibly would affect the process of dyeing the wool in its second life. Moreover, the washing needed during the use stage (wearing) of apparel made of wool could make the fibres become yellow/darker, preventing the reuse of the clothes.

One example that relates to recyclability is the use of carbon black as a pigment in plastics during production, which can result in severe interference with the identification and sorting of plastics according to polymer type when using near-infrared (NIR)-based automatic plastic waste sorting. This is due to the carbon black absorbing most of the radiation, thereby making the analysis of the reflected spectrum very difficult or impossible, and thus substantially decreasing the sorting efficiency[150]. More examples for possible SoCs under Art. 2(27) (d) are reported in **Table 4**.

Material recovery is defined in the Waste Framework Directive as 'any recovery operation, other than energy recovery and the reprocessing into materials that are to be used as fuels or other means to generate energy. It includes, inter alia, preparing for reuse, recycling and backfilling'. An example of substances affecting this product aspect is related to the amount of materials that can be recovered without a substance hindering the second (or third, fourth, etc.) use of that material. Standards EN 45555 and ISO 22628 suggest a calculation method of the percentage of a product that can be recovered and later reused. In this case, a product with a high percentage of recovery of materials would be one where hazardous substances or substances hindering recyclability are locked in one component of the product, which is easily accessible on dismantling. Thus, there is the opportunity to collect the parts of the product which are useful and depolluted, ready for their introduction into another product, such as the use of labels which are easily removable in PET bottles. The PS team would need to assess if there are substances which are used that affect the recovery of materials, including critical raw materials, as suggested by point (h) of Annex I to the ESPR.

Finally, the PS team should also consider any links between substances and the availability of consumables needed for the product's proper use and maintenance, as expressed in point l) of Annex I to the ESPR. An example could be related to the case of air conditioning equipment, which needs to be periodically refilled with refrigerant gas. In this case, there may be impediments to the refilling if the refrigerant gas has been phased out or simply because it is no longer manufactured for other reasons, which could directly or indirectly be related to substances.

Product aspects: (h) energy use and energy efficiency; (i) water use and water efficiency; (j) resource use and resource efficiency

These product aspects address the use of energy, water, and other resources throughout the life cycle of the product. In this context, **resource use** is 'the use of raw materials, mainly abiotic (minerals, metals, fossils), in all lifecycle stages'; **resource efficiency** is 'the benefit obtained from the use of natural resources. In this theoretical equation, benefits can be represented by economic goods, services provided, social gains, etc.; whereas the use of natural resources can be accounted for as the volumes, kWh or masses of resources consumed (materials, water, energy) or used (land, air, ecosystems), or the impacts derived from the use of resources'[151].

The analysis of these aspects is already considered when performing the Life Cycle Assessment of the Base Case of the product under study; however, additional analysis is envisaged, to the extent that available information allows, with respect to the link between substances and energy, water and resource use and efficiency. The PS team should thus investigate whether substances are used

[150] Ian Mabbett, Jon Elvins, Cathren Gowenlock, Paul Jones, David Worsley, 2013, Effects of highly absorbing pigments on near infrared cured polyester/melamine coil coatings, Progress in Organic Coatings 76.

[151] 2013 report from BIO Intelligence Service for DG for Enterprise and Industry.

that are responsible for a sub-optimal use of energy, water and other resources. For this, it is important to stress that a life cycle approach should be taken, in order to avoid burden shifting.

It could occur that the use of a certain substance requires a higher energy use for its production (compared to another substance) but enables one to save energy during the use stage (e.g. lower water temperature for washing, less frequency of charging for electronic products), resulting in an overall lower energy consumption. Similar trade-offs may be exemplified by the use of glycerine in cosmetic products, for which a comparative analysis is available on the life-cycle impacts of natural glycerine derived from Brazilian soybean, natural glycerine derived from European soybean, and synthetic glycerine[152]. The results showed that synthetic glycerine needs more energy for its production compared to its natural counterparts. However, the LCA conducted also highlights that synthetic glycerine uses considerably less land (in the "land use" impact category of LCA) than natural glycerine. This example stresses the importance that the PS team should place on analysing the full life-cycle and all categories of impact of the substances and/or products, to ensure a good understanding of the trade-offs and avoid burden shifting across life cycle stages and/or environmental areas of impact.

Another example comprises the use of polyfunctional reactive dyes in textiles which, as reported in the Best Available Techniques (BAT) Reference Document for Textiles, require less salt, less water, less energy and in some cases zero detergents for the rinsing operations, compared to the resource needs of traditional reactive dyes. A shorter processing time may be obtained on certain substrates by combining the pre-treatment and dyeing steps using polyfunctional dyes that fix colours at 90 °C. Savings of up to 40% in water and energy consumption, and more than 30% of salt, have been claimed in such cases (Roth et al., 2023).

Product aspect (k): recycled content

This product aspect from Art. 5(1) should be analysed making the necessary links with the Annex I product parameter (h) on '*use or content of recycled materials and recovery of materials, including critical raw materials'*.

The ESPR does not provide a definition for **recycled content;** however, this is defined in Commission Decision (EU) 2016/1332, establishing the ecological criteria for the award of the EU Ecolabel for furniture. Here, **recycled content** is defined as '*the proportion, by mass, of recycled material, from pre- and post-consumer waste, in a product or packaging*'. Regulation (EU) 2023/1542 on batteries and waste batteries does not provide a definition but addresses recycled content, and sets specific targets, in its Article 8 "Recycled content in industrial batteries, electric vehicle batteries, LMT batteries and SLI batteries".

Recycled content may be affected by substances in the sense that the properties of a product may suffer from substances contained within recyclates from not only post- but also pre- consumer waste. An example of this case is in the steel industry, where the content of certain elements, such as copper, may hinder the properties of the recyclate product. According to Su and Assous[153], although more scrap could be sourced in the EU (via better collection practices and less exports of steel scrap), a certain amount of virgin iron is still required as an input even to the most advanced technology for steel production from secondary sources) (e.g., 17% when using the most advanced electric arc furnace (EAF)). Hence, for up to 83% of the steel recyclate, "contaminants" such as copper, molybdenum, etc. from previous product specifications and life cycles need to be checked with respect to the needs for the new life cycle use and specifications. If these chemicals/ alloys are not appropriate for the new specifications, either this portion of the recyclate may not be used for

[152] Quantis, 2020, Make up the future – Levers of change for a sustainable cosmetics business.

[153] Su, R. & Assous, A.: Starting from scrap. The key role of circular steel in meeting climate goals. Report by Sandbag Climate Campaign ASBL, 2022; Online available at https://sandbag.be/wp-content/uploads/Sandbag-Starting-from-Scrap.pdf.

the particular application, or the metals may have to be removed, depending on technical/economic feasibility.

Regarding textile products, it is acknowledged that longer fibres increase the yarn strength. Mechanically, recycled fibres are shorter than virgin fibres; hence, during yarn spinning, shorter fibres result in the production of lower strength yarns[154].

Plastics also exhibit reduced performance of the recycled materials due to the presence of impurities of a diverse nature that ultimately limit the recycled content in products. Van Velzen et al. (2020)[155] assessed the effect on impact resistance of mechanically recycled polyethylene (rPE) due to the presence of polymeric contaminants from different waste flows or due to residues from labels.

As already reported in Section B, potential limitations to recycling may arise from product and waste legislation, since recycled materials or reused products may not be able to comply with existing requirements applicable to products currently being placed on the market.

Product aspect (o): environmental impacts, including carbon footprint and environmental footprint

The analysis of the performance of the Base Case in relation to product aspect (o) of Art. 5(1), i.e. '*environmental impacts, including carbon and environmental footprint*' and its link to the product parameter (f) from Annex I, i.e. '*use of substances, and in particular the use of substances of concern*', should be performed via the analysis of the Life Cycle Impact Assessment (LCIA) of the Base Case, and the consequent interpretation of results by assessing each impact category and, in particular, the impact categories where substances have a relevant impact.

According to Art. 2(24) of the ESPR, '*environmental footprint means a quantification of the environmental impacts resulting from a product throughout its life cycle, whether in relation to a single environmental impact category or an aggregated set of impact categories based on the Product Environmental Footprint method established by Recommendation (EU) 2021/2279 or other scientific methods developed by international organisations, widely tested in collaboration with different industry sectors and adopted or implemented by the Commission in other Union law*'. In addition, Art. 2(25) defines 'carbon footprint' as '*the sum of greenhouse gas emissions and greenhouse gas removals in a product system, expressed as CO_2 equivalents and based on a life cycle assessment using the single impact category of climate change*'.

ESPR refers to the Product Environmental Footprint (PEF) method established by Recommendation (EU) 2021/2279[156] as one of the methods to assess the life cycle environmental performance of products on the market. The EF 3.1 impact assessment method (Andreasi Bassi et al., 2023)[157] suggests a set of 16 impact categories to be addressed when conducting a LCA study (such as *Climate Change, Water Use, Resource Use (fossil and minerals and metals) and Land Use),* expressed by indicators and related units of measure. The EF 3.1 impact assessment method also includes the impact categories *Human toxicity (cancer and non-cancer)* and *Freshwater ecotoxicity*, which have a different focus compared to other approaches for the safety assessment of chemicals. Indeed, the PEF (and LCA approaches in general) addresses indirect toxicity impacts on

154 Wood, E., Overview of Wool Yarn Manufacture, Woolwise, The Australian Wool Education Trust, 2009, https://www.woolwise.com/wp-content/uploads/2017/07/Wool-482-582-08-T-02.pdf.

155 Thoden van Velzen EU, Chu S, Alvarado Chacon F, Brouwer MT, Molenveld K. The impact of impurities on the mechanical properties of recycled polyethylene. Packag Technol Sci. 2021; 34: 219–228. https://doi.org/10.1002/pts.2551.

156 Commission Recommendation (EU) 2021/2279 of 15 December 2021 on the use of the Environmental Footprint methods to measure and communicate the life cycle environmental performance of products and organisations (OJ L 471, 30.12.2021, p.1).

157 Andreasi Bassi S., Biganzoli F., Ferrara N., Amadei A., Valente A., Sala S., Ardente F., *Updated characterisation and normalisation factors for the Environmental Footprint 3.1 method*. Publications Office of the European Union, Luxembourg, 2023, doi:10.2760/798894, JRC130796.

humans and the environment *via* different compartments, rather than placing a specific focus on direct exposure. The PEF method (and LCA overall approach) provides an overall toxicity footprint, summing the contribution of different chemicals that have been used in the production and consumption of a product, according to the latest toxicity impact assessment methods and characterisation factors available in LCA. Thus, these indicators are used to assess the overall value chain, comprising inputs, processes, emissions, etc.; note that the overall value chain approach does not replace the hazard assessment and risk metrics that are utilised in REACH and CLP. According to the PEF method, the results of the LCA should be left as individual indicators, i.e. as characterised results at midpoint[158]. In addition, for the interpretation step, the normalised and weighted results should be considered, in order to identify the most relevant impact categories on the single overall score.

In order to analyse the product aspect o) '*environmental impacts, including carbon footprint and environmental footprint*', the PS team should utilise the **PEF method** or other LCA-based scientific methods of similar repute, which have been developed by international organisations, widely tested in collaboration with different industry sectors and adopted or implemented by the Commission in other Union law. For more details about the general analysis for the environmental footprint please refer to the report of Task B1: 'Developing a method for the assessment of life-cycle environmental impacts of products, and integration in or relation with the Methodology for the Ecodesign of Energy-related Products'[159].

The present method for product aspect (o) builds on the Task B1 report and proposes an **additional analysis** specifically focused on substances. The analysis should take place in addition to the overall hotspot analysis that is performed in Task 5 of the MEErP (and that is the object of the Task B1 Method). The analysis proposed for product aspect o) is suggested to focus on two parts of the LCA: (i) the life cycle inventory (LCI) and (ii) the life cycle impact assessment (LCIA).

The final aim of such additional analyses is to find the **relation between substances, their concentrations (or amounts) and the impacts on the environmental footprint of the Base Case**, for each individual impact category. This should be conducted to the extent feasible, according to the information available and collected/quantified in Section A of the present method for the Base Case.

Life Cycle Inventory (LCI)

The additional analysis needed to build the LCI includes the information collected on substances along the life-cycle stages of the product, as considered in the Base Case (information collected in Section A of this method).

As a general principle, for each life cycle stage and each manufacturing process, the LCI should clearly represent the flows related to the production of the substances, and the emissions resulting from their use, throughout the whole life cycle, as mapped in Section A for the Base Case.

This task can be performed using datasets representing the production of substances identified in Section A as part of the raw materials use (e.g. production of sodium chloride for a defined amount, as required in the dyeing process of textile products) and introducing emissions (e.g. emissions to water of sodium chloride for a defined amount deriving from the dyeing process). [NB For a description of limitations encountered in emissions modelling of un-abated/un-degraded substances, please see Section A].

[158] The characterization is the calculation of the magnitude of the contribution of each classified input/output to their respective EF impact categories, and aggregation of contributions within each category.

[159] Gonzalez Torres, M., Kouloumpis, V., Rodriguez Manotas, J., Magrini, C., Senatore, V. et al., Developing a method for the assessment of life-cycle environmental impacts of products, and integration in or relation with the Methodology for the Ecodesign of Energy-related Products, Publications Office of the European Union, Luxembourg, 2025, https://data.europa.eu/doi/10.2760/3515898, JRC143211

In this way, the resulting LCI should have a suitable level of granularity to enable the assessment of the contribution of substances to the environmental footprint of the product.

The LCA practitioner may typically encounter two possible scenarios:

- Disaggregated datasets may be available for specific processes related to the product (e.g. dyeing) in databases for LCA. Such datasets may be adapted, to adequately represent the substances identified in Section A for the Base Case.
- Disaggregated datasets for specific processes related to the product (e.g. dyeing) are not available: the suggestion for the LCA practitioner is then to create disaggregated datasets, following the procedure described above.

The second scenario may require additional analysis, since also resources, energy consumptions and waste treatments need to be reported in a disaggregated manner in the newly-created dataset. A further limitation of the second scenario is the reduced possibility of being able to representing a full picture for certain processes. Datasets from available databases may complement the analysis on substances performed in Section A, particularly for the estimation of substances emitted as degradation products, as well as for other relevant inputs and outputs to the process, which would otherwise potentially not be noted.

In a simplified broader approach as described above, information on relevant substances used along the life cycle of the product under study may be missing, thereby limiting the possibility to perform a full LCA for the analysis of product aspect (o).

Life Cycle Impact Assessment (LCIA)

In order to establish the link between the Life Cycle Impact Assessment (LCIA) and product-relevant substances, a **top-down approach** is proposed. It is suggested that the PS team investigates the possibility to trace back along the value chain the substances responsible for the calculated results of the impact category under investigation, in order to identify precisely the relevant processes of the LCA of the Base Case (e.g. via layered graphical representation provided by LCA calculation software, where available).

This type of assessment allows the PS team firstly to focus solely on the substances that are in the scope of the performance requirements (i.e. those that are strictly related to the Base Case life cycle stages), and secondly to disregard the substances that are irrelevant for the Base Case (e.g. flows outside the designated system boundary, e.g., related to the construction of the infrastructure for energy distribution). Moreover, this assessment allows an enlargement of the analysis of substances performed in Section A, using the inventory of secondary data contained in the disaggregated datasets used for the LCA, if available.

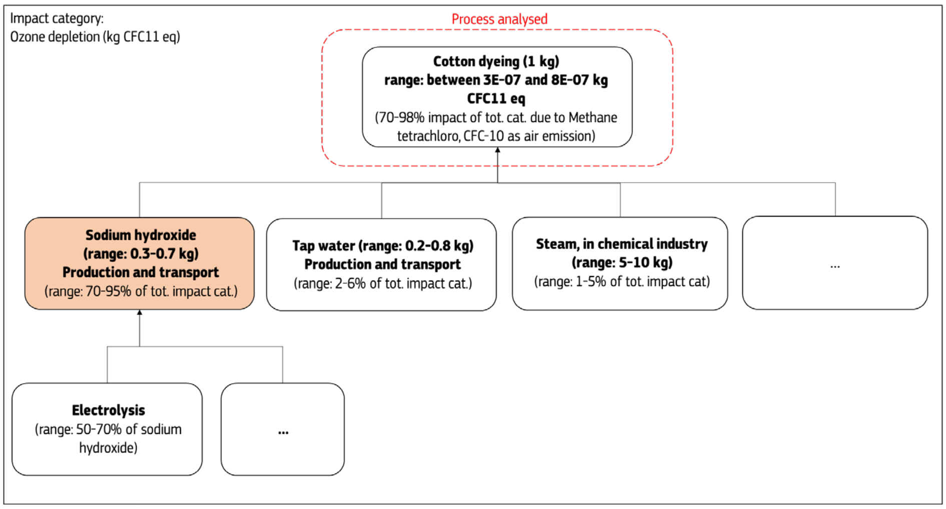
In this way, when following the PEF guidance for the identification of the most relevant processes and elementary flows, it should be possible for the PS team to identify the contribution of the production of substances and their emissions along the life cycle of the product.

As an example, **Figure 9** shows the impact result at midpoint (i.e. characterised midpoint results) of the cotton dyeing process, carried out using a disaggregated dataset available in a database (via der subscription), in which it is possible to identify the substances with the largest contribution to the environmental profile of the process. In this example, the analysis was performed using the EF 3.1 method (non-regionalised) for the impact category Ozone depletion. During the investigation of the characterised results, substances used in the process resulted in a global impact ranging from 70-98% for the Ozone depletion category. This is an example where the most relevant contribution is provided by air emissions of methane and tetrachloro CFC-10. The substance that contributed to the highest impact is sodium hydroxide (used to increase the pH during the dying process), the production of which provides the highest contribution to the emissions of methane, tetrachloro CFC-10 in air, via a direct emission of the sodium hydroxide productive process.

The PEF guidance recommends focussing on the most relevant processes, i.e. when the production of a substance contributes to 80% or more of the total impact, expressed as a characterised EF result. Where this happens solely for one or a limited number of the most relevant impact categories, it is suggested, as an **additional step**, that the identification of the hotspots for substances is analysed in the Preparatory Study considering the **single overall score** (i.e. the sum of the weighted EF results of all environmental impact categories). Carrying out this further assessment is suggested, in order to understand the global contribution of the substance to the life cycle of the product and to assess the **relative relevance** of the substance for the Base Case, also considering other flows (e.g. energy consumption) investigated in the broader context of the Preparatory Study. The use stage may be excluded in this refined assessment if it dominates the results for reasons not related to the use of substances (e.g., consumption and emissions). However, given the influence of the inventory data and of the uncertainty associated with background datasets, it is suggested that the LCA practitioner checks the presence of any mistakes in the computations of the LCI, and to assess the variations of the impact, depending on the choice of the dataset via a sensitivity analysis.

Regarding **toxicity categories**, it is generally not possible to rank substances based on toxicity results because of the uncertainty in the characterisation factors (CFs): "[…] *contributions of 1%, 5% or 90% to the total toxicity score can be interpreted as essentially equal, but significantly larger than those of a chemical contributing to less than 1 per thousand or less than 1 per million of the total score*" (Fantke et al., 2015[160], Rosenbaum et al., 2008[161]).

Figure 9. Graphical representation on the characterised results (partial representation) of the LCA model with disaggregated datasets for an example process related to textile (**top-down approach**).



Source: JRC's own elaboration based on an example dataset analysed with EF 3.1 method (non-regionalised).

Note: Shown in orange: chemicals in scope of possible Ecodesign measures (hotspots). For each process, the amount needed for the Functional Unit is reported in parenthesis. Ranges of results rather than actual values are reported for confidentiality reasons.

It is therefore proposed to the Preparatory Study team to follow a tiered approach to address the toxicity results of substances, where those substances whose contribution is greater than 0.1 % of

160 Fantke, P., Huijbregts, M., Margni, M., Hauschild, M., Jolliet, O., McKone, T.E., Rosenbaum, R.K., van de Meent, D., 2015. USEtox® 2.0 User Manual (Version 2), http://usetox.org.

161 Rosenbaum RK, Bachmann TM, Gold LS, Huijbregts MAJ, Jolliet O, Juraske R, Koehler A, Larsen HF, MacLeod M, Margni MD, McKone TE, Payet J, Schuhmacher M, van de Meent D, Hauschild MZ (2008): USEtox - The UNEP-SETAC toxicity model: Recommended characterisation factors for human toxicity and freshwater ecotoxicity in life cycle impact assessment. The International Journal of Life Cycle Assessment 13: 532-546.

the characterized results are identified, along with the most relevant life cycle stages. Then, the origin of the most-contributing substances should be investigated, in order to discriminate emissions of substances related to inventory data included by the LCA practitioner from those related to background datasets. The former are proposed to be flagged in the Preparatory Study.

An analogous approach is suggested also for the impact category Particulate matter, where the human health effects associated with exposure to PM2.5 is measured in terms of Disease incidence, thereby also providing a measure of the health hazards associated to substances.

The aim of this exercise in LCA modelling, as far as substances are concerned, is to determine areas where there would be opportunities to reduce the overall environmental footprint by specifically acting on substances (i.e., where product requirements may be desirable and feasible). Substances, where their impact results primarily from chemical safety concerns, could be flagged in the Preparatory Study report for potential subsequent action under the relevant specific legislation such as REACH, the POPs Regulation, etc. In situations where a performance requirement is suggested in a Preparatory Study for a substance, for reasons other than primarily their chemical safety, benefits in terms of a possible reduction of the toxicity footprint, brought about by, for instance, the substitution of a specific substance, could be determined and reported as a result of this LCA, as further explained in subsequent sections.

To the extent feasible, the Preparatory Study would need to assess what is the link (if any) between environmental footprint results and **product parameter (f) of Annex I** regarding '*use of substances, and in particular the use of substances of concern, on their own, as constituents of substances or in mixtures, during the production process of products, or leading to their presence in products, including once those products become waste, and their impacts on human health and the environment'*.

The link between environmental footprint results and substances can be established by referring the impact value for the impact category – as calculated for the specific substance identified via the hotspot analysis - to the corresponding input/output amount of the substance for the relevant life cycle stage (as determined in Section A, based on the linearity underpinning the relationship between LCI and LCIA).

Product aspect (p): expected generation of waste

Based on Directive 2008/98/EC and considering the definitions for 'waste' and 'hazardous waste', the **expected generation of waste** could be defined as the typical generation of any (especially hazardous) substance or object along the whole life cycle that the holder discards, intends, or is required to discard.

This aspect is linked to the product parameter (r) from Annex I: '*amounts of waste generated, including plastic waste and packaging waste and their ease of reuse, and amounts of hazardous waste generated*'. The PS team should investigate if there are substances where a particularly relevant amount of waste generation is directly associated with the use of specific substances during the manufacture of the product, or with the materials contained in the product. Particular attention should be given to identifying substances present in waste at concentrations which would lead to its classification as hazardous waste, or as "POPs waste", since these pose the highest environmental and human health concerns and are particularly demanding in terms of their control and treatment.

It should be noted that in the LCA, waste outputs may be also considered if the analysis is performed taking into account such system boundaries (End-of-Life).

In particular, plastic waste polluted with certain substances should be taken into account, particularly regarding SoCs that may hinder recycling and reuse. Packaging aspects are within the scope of the ESPR, where they are addressed already via the Packaging and Packaging Waste Regulation (PPWR). Along this line of argumentation, in order to reduce packaging waste in general, also taking into consideration parameter (t) of Annex I, '*lightweight design*' would have a positive impact on the '*reduction of material consumption*', among other aspects regarding '*material savings, recycling and other circularity aspects, and waste reduction*'. Substances impacting on these parameters should be investigated by the PS team.

An example of a performance requirement in relation to substances and expected generation of waste could be related to the '*setting of requirements for minimum process of waste reuse and/or reward the incorporation of content originating from recycled or secondary materials, where appropriate*' as in EU Ecolabel criteria for hard covering products[162]. In this case, criteria on the reuse of waste are included for these products. For instance, the criteria require the provision of an inventory of the process waste for certain materials and the reuse of certain percentages of wastes (i.e. '*At least 80 % by mass of the process scrap generated from natural stone processing operations onsite shall be reused in other applications or stored onsite in preparation for future sale*').

Two examples are reported in the Best Available Techniques (BAT) Reference Document for Textiles that explore further perspectives of this product aspect:

- 'Regarding the use of phosphonates (e.g. DTPMP, HEDP), as substitutes of [other complexing agents], it should be noted that the majority of phosphonates are not biodegradable, but instead are bioeliminable. Due to the very slow degradation and the small number of phosphonate-utilising species of microorganisms, it is assumed that phosphonates cannot be mineralised in conventional biological wastewater treatment plant (WWTPs), aerobically or anaerobically. Accordingly, phosphonates remain in adsorbed form in the sewage sludge in their original form and can only be completely oxidised ('mineralised') and thereby removed from the environment by combustion of the sewage sludge'.
- 'For monofunctional dyes, the fixation rate is approximately 60 % (with an exhaustion rate of about 70 %), which means that 40 % of the dye applied is lost in the effluent'.

To summarise: it should be noted that the method to establish the impact, synergies and trade-offs between substances and product aspects listed in Art. 5(1) should start from Task B2 (which only takes into account circularity aspects, see more details in this task) and be complemented with the explanations in this section.

5.1.2 Proposed approach for setting performance requirements

The decision of whether and how to set performance requirements on the presence or use of substances, should be based on the extent to which substances affect one of the product aspects in Art. 5(1) of the ESPR.

To optimise the work to be performed by the PS team, it is recommended to start with a literature review and a stakeholder consultation early on in the process, in order to identify substances that are known or suspected to affect one or more of the product aspects. The analysis presented in the following paragraphs should be performed only on those identified substances which are known to pose or suspected of posing problems to one or more of the product aspects under Art. 5(1) (i.e. **target substances**), rather than on the full spectrum of substances used in the product or in its life cycle. The analysis should be performed on one product aspect at a time.

As a general consideration, defining a *general* method for setting performance requirements on substances, associated with their impact on specific product aspects, seems an impossible task,

[162] Commission Decision (EU) 2021/476 of 16 March 2021 establishing the EU Ecolabel criteria for hard covering products https://eur-lex.europa.eu/legal-content/en/TXT/?uri=CELEX%3A32021D0476#:~:text=The%20EU%20Ecolabel%20criteria%20for%20hard%20covering%20products,reduced%20emissions%20to%20air%2C%20and%20reduced%20water%20consumption.

given that, for defining specific concentration thresholds or use conditions, a clear link between the substance and a product aspect needs to be defined and understood. This is expected to be, in most cases, specific to the particular substance and product aspects being considered. However, some general considerations can be provided, without the prescription of any specific rules, since the PS team will essentially be confronting an ad hoc process.

As a starting point, for the selected substances, the PS team should consider the **Base Case** product, as described in Section A of this report, as well as the distribution/ranges of the concentrations of substances (if available) and performance of the product under study, i.e. from the **worst-case product** in terms of substances**, moving to the average product** and finally to **a best performing product**.

Proposed performance requirements, in terms of substances, could follow different levels of ambition, via tiered or phased approach regarding relative ambition levels over time, as has been used on various occasions in setting product requirements in the Ecodesign Directive's "daughter" regulations. As such, where different requirements would be set in the delegated act, but would only come into application in a staggered manner, i.e., at different moments in time, or even be identified as "Best Available Techniques" regarding towards a possible future revision of the act. Whether the data requirements and associated analyses to allow the identification and proposal of several tiers for substance-related the performance requirements would occur via the analyses made and the interplay between Tasks 5, 6 and 7 of the MEErP.

The advantage of tiered approaches over time to product-related requirements is that they enable stakeholders, particularly producers, to prepare well in in advance of the measures coming into effect. The Base Case, the average product (AP), and the best performing product (BP) should all be investigated from the point of view of their chemical composition (i.e. the concentration of the relevant substances). In addition, their performance should be investigated in terms of each specific product aspect (e.g. durability, expressed - for example - in terms of the technical lifetime).

While the starting point is the Base Case (where the Bill of Material is defined, if possible, according to the weighted average on the market), the average product (AP) and the best performing product (BP) are defined as virtual products consistent with the Base Case, i.e. with the same BoM of the Base Case, but with a different composition of substances (in the product and along the life cycle), and especially SoCs. Usually, the content of relevant substances in the average product and the best performing product is lower compared to the Base Case; or, for example, in the BP product, the substance may even be totally absent. The best performing (BP) product represents the direction in which to go in terms of the presence and the number of relevant substances in the product and its life cycle.

In particular, if an intentionally added substance with a specific function is identified as negatively affecting one of the listed product aspects, the PS team should analyse:

- the volume of the substance used in the EU for that function and in that product / product family;
- whether the same function is achieved by means of other substances in alternative product compositions;
- the availability of other alternative substances in the EU market;
- whether the use of other substances would require adaptations to the technology used;
- whether the use of other substances would imply significant differences in costs.

If alternatives seem to exist for a substance identified as negatively affecting at least some of the affected product aspects, the PS team should proceed with an evaluation of alternatives and possible substitution options, as explained in Section C2, below. However, if there is insufficient information on the presence and frequency of the concentration of a substance under consideration for setting a performance requirement, or if the evaluation of alternatives via Section C2 does not provide sufficiently robust evidence to support a performance requirement (e.g., proposing a restriction), the resulting action(s) could be:

- To propose instead a *mandatory information requirement* via ESPR on such a substance, if it qualifies as a substance of concern. As such, this action would enable the tracking of its presence in products within scope and to gather data that could be usefully considered for potential future restrictions, if needed.
- Not propose any measure, at that point, owing to the incompleteness of the evidence base (possibly to be revisited in the comparison of options during the regulatory Impact Assessment phase).

In some cases, potential target substances for a performance requirement under the ESPR may stem from impurities that remain in the product following the addition or use of a functional chemical. An example of this can be found in certain textiles, where heavy metals can remain as impurities due to their use as catalyst in dyes (Roth et al., 2023)[163].

Functional requirements

The reference values in the Base Case, average product and best performing product should also be defined considering the **function of the substances** as identified in Section A. These reference values should then be taken into account when considering any setting of restrictions, e.g. in terms of maximum concentration values that have an impact on performance, so as to ensure that this does not result in any (significant) reduction in the performance of the product.

As recommended in Section A, a list of possible technical functions (TF) that a substance may provide is available from ECHA's guidance R.12 (ECHA, 2015). Once the technical function has been identified, the functional requirements should be described through **qualitative or quantitative criteria and/or indicators**.

According to ECHA's guidance on the preparation of an application for authorisation (ECHA, 2021), examples of **functional requirements** to be taken into consideration may include:

- critical substance properties related to the desired equivalent function;
- quality criteria;
- process and performance constraints;
- customer requirements or legal requirements for technical acceptability.

Table 9 below provides an overview of source of information for functional requirements of the target substance and on the technical/economic feasibility.

Table 9. Sources of information for functional requirements and technical/economic feasibility.

Source	Description	Minimum data requirements
Publicly available data sources		Substances: Quantitative criteria and/or indicators
ECHA	— R.12 Guidance – Use descriptors	

163 Joze Roth, Benoit Zerger, Damien De Geeter, Jorge Gómez Benavides, Serge Roudier, Best Available Techniques (BAT) Reference Document for the Textiles Industry, Publications Office of the European Union, Luxembourg, 2023, doi:10.2760/355887, JRC 131874.

Source	Description	Minimum data requirements
	— Annex XV dossiers supporting identification of SVHC or Restriction proposal — Supporting documentation for inclusion in Annex I to POP Regulation — Applications for Authorisation (AfA) dossiers, with specific regard to Analysis of Alternatives (AoA) and Socio-Economic Assessment (SEA) — Investigation reports upon the request from the EU Commission	related to functional requirements of the target substance and to the technical economic feasibility of substitution
European Commission/ JRC	BREF	
OECD	— OECD Substitution and Alternatives Toolbox (SAAToolbox)	
Chemsec	— SIN List — Marketplace	
Other projects	— Massachusetts Toxics Use Reduction Act, TURA — Pharosproject — Cleaner solution database — SUBSPORTplus Portal — Swedish Centre for Chemical Substitution	
Value chain based information		
Consultation within PS	— Information related to the functional requirement of the target substance and to the technical / economic feasibility related to the setting of performance requirements or substitution can be gathered from the stakeholders involved in the PS	

Source: JRC's own elaboration.

General approach to defining limit values for substances, or other limitations, associated to specific product parameters

Following the identification of a link between a substance and a specific product parameter, a quantitative or semi-quantitative definition of the relationship between the amount or concentration of the target substance and the product parameters under consideration should be investigated, to the extent possible. Obtaining such an understanding is essential prior to being able to propose any limit value, a full ban/ restriction or other form of limitation on its use.

Limit values for amounts or concentrations of substances, where relevant, are set related to product aspects, where the presence of such substances has been shown to be correlated with an "unacceptable worsening" of the product aspect being addressed. The substance's presence in the materials is, for practical and analytical purposes, assumed to be homogeneous (i.e., the concentration is assumed to be uniform). As such, the approximation is made that any substance concentration (limit value) is applicable for the whole of the relevant material in the product. In addition, limit values may likewise be set for substances that are present along the life cycle, which have the same effect of "unacceptable worsening" of the end product.

However, it should be noted that substantiating the meaning in the ESPR context of what constitutes an "unacceptable worsening" carries a degree of subjectivity; this will depend on the product aspect considered. For example, product aspect (m) *recyclability* could be understood as the concentration of a substance that leads to the discarding of the material, as opposed to its acceptance for recycling in the recycling plants. For each particular case, an understanding of the legal context, the market and its expectation regarding the product, as well as other socio-economic, consumer behavioural and environmental considerations play a role in determining this. The inputs received from stakeholder consultation during the Preparatory Study will therefore provide key information on these issues. In this sense, Article 5(11) of the ESPR, regarding prerequisites for possible ecodesign requirements, are essential to duly consider, i.e., "a) there shall be no significant negative impact on the functionality of the product, from the perspective of the user" and "c) there shall be no significant negative impact on consumers in terms of the affordability [...]".

For all product aspects, except for those under letter (o) *environmental impacts, including carbon footprint and environmental footprint,* the identification of tentative concentration limit values for substances along the life cycle is performed concurrently with the data collection from stakeholders or from literature. For example, for substances that affect product aspect (m) *recyclability*, the limit threshold would be informed by the alert concentration (c_{alert}), as described in Section B.

Target Substance(s)

The identification of target substances is triggered by the comparison of the concentration of the substances in the Base Case(s) i.e. by comparing c_{BC}, as defined in Section A for functional substances and for non-intentionally added substances, i.e., potentially affecting specified product aspects, with the identified tentative limit values (i.e. $c_{BC} \geq c_{limit}$).

If the definition of the concentration of substances in the Base Case followed the worst-case approach, and links to relevant product aspects are identified with such substances, it is plausible that at least some of these concentrations correspond to the identified limit values. Thus, these substances would be identified as target substances.

As a general indication, the **decision to propose a performance requirement on a substance** (e.g. a limit value) will depend on the impact of the substances in the product aspect concerned, on the product group under investigation and to what extent such a limit-based action is expected to provide a significant overall benefit in terms of its environmental performance. Hence, representative data are essential for the PS team in order to be able to propose any performance requirements.

For the product aspect letter (o) *environmental impacts, including carbon footprint and environmental footprint,* a possible procedure for the identification of the hotspot(s) is proposed in the previous section (i.e. Section 5.1.1), based on the PEF methodology. The identified hotspots are determined by the input and output amounts of substances to the processes, included those not remaining in the product, defined here as amounts along the life cycle (a_{LC}). These substances are addressed in Section A.

Reference impact value

To understand whether the identified hotspots from the LCA that relate to substances should be considered as target substances, and thus potentially be proposed to be addressed via ecodesign measures, a comparison with a **reference impact value** is suggested, as described below.

The **reference impact value** may be defined, for example, for an input amount of substance by calculating the environmental impact for a specific impact category due to the use of an alternative substance in a certain manufacturing process, along with the percentage contribution of the use of this substance to the environmental footprint of the Base Case (as modified). Such alternative substance(s) need to fulfil the same function as the substance under investigation and would correspond to the average and the best performing substances available on the market.

Information for conventional processes or substances already available on the market with sufficient capacity are also reported in sector-relevant Best Available Technique Reference documents (BREFs). Alternatively, the reference impact value could be calculated using disaggregated datasets from LCA databases representing manufacturing processes for, e.g., 1 kg of textile product, as the average impact contribution of substances (both as input and emissions) to the assessed processes.

Where the calculated percentage contribution of the alternative substance to the environmental impacts of the modified Base Case is lower than percentage contribution caused by the identified 'hotspot' substance, the reference impact value may be used to determine the corresponding **proposed limit input amount (e.g. in grammes)** of the substance being investigated. Where this applies to a certain manufacturing process the value in question may be interpolated, thanks to the linearity underpinning the Life Cycle Inventory and Life Cycle Impact Assessment. This is illustrated in Equation 1 below and the Annex VI "Case Study" accompanying the present report, where a numerical example for the application of the formula is shown.

$$Proposed\ limit_{subst,x} = \frac{(\mathrm{a}_{LC,subst,x} \times reference\ impact_{alt\ subst})}{impact\ result_{subst,x}} \qquad \text{(Eq. 1)}$$

Where:

$a_{LC,subst,x}$ is the input amount (g) of the 'hotspot' substance in the current Base Case to a certain manufacturing process;

$reference\ impact_{alt\ subst}$ is the characterised result for the impact category due to a defined input amount of alternative substances to a certain manufacturing process;

$impact\ result_{subst,x}$ is the characterised result for the impact category of the 'hotspot' substance.

Similarly, limits to input amounts may be defined in order to reduce the effect(s) caused by the corresponding emissions. Here the PS team should note the limitations concerning the impact categories that provide hazard-related metrics, as described above.

The technical feasibility of any proposed limit values regarding the substance should then be validated via stakeholder consultation and engagement. Alternatively, or in addition, the assessed average and best performing substances may be assessed via the method described in Section C2 of this guidance, where all the impact categories and all the life cycle stages are encompassed to avoid regrettable substitution.

As already mentioned, given the influence of the inventory data, the background datasets and the characterisation factors on the results of the LCA Environmental Footprint, it is suggested to check the inventory data and the influence of the choice of datasets via a sensitivity analysis. Improved environmental profiles of possible alternative substances (chemical substitution) or technologies (functional substitution) should be considered in Task 6 'Design options' of the Preparatory Study as a potential reference and weighted with regard to the **overall** (i.e., for **all** the product aspects, not solely "substance-related") additional improvement options and potential actions being considered.

In Tasks 5 and 6, modelled improvements coming from alternative substances should be considered as insignificant, where the improvement is lower than the threshold of the minimum uncertainty on the overall model. An example of such an approach is detailed in the study "Comparative Life-Cycle Assessment of nickel-cadmium (NiCd) batteries used in Cordless Power Tools (CPTs) vs. their alternatives nickel-metal hydride (NiMH) and lithium-ion (Li-ion) batteries" (Mudgal et al., 2011[164]).

The setting of thresholds, or specific conditions of use for the target substance, may require manufacturers to make changes for example, in the production processes and/or in the product's composition. The trade-offs between technical/economic feasibility and the functional requirements must also be considered (to this end, the approach proposed in Section C2 to evaluate the trade-offs associated with the alternatives should be considered). The outcome may result in proposing performance requirement(s), if the assessment gives a positive result. Alternatively, if the assessment gives a negative result, the next step is to reconsider the performance requirements. For a comprehensive overview of the process, please refer to **Figure 10**.

In summary, the PS team may be able to propose performance requirements on substances in relation to the product aspects defined in Art. 5(1), following the summary steps detailed below. It is suggested that the type of performance requirements to consider should follow the example of current ecodesign and other product-specific regulatory measures, such as those in REACH, the EU Ecolabel or Green Public Procurement, whereby consultation and engagement with stakeholders across the spectrum of actors is an essential part of the process.

The main **steps for setting of possible performance requirements on substances via restrictions, including the setting of limit values,** are summarised as follows:

- **Step 1**: Identify **the product aspects** relevant for the product group under analysis (this is carried out in Task 4 of the MEErP – for details see the report in Task B2 'Method for the assessment of circularity aspects and integration in or relation with the Methodology for the Ecodesign of Energy-related Products (MEErP)' and the further analysis as described above for other product aspects including substances).
- **Step 2**: Identify substances (referred to as **target substances**) suspected to have an impact on the relevant product aspects identified.
- **Step 3**: Establish the **relationship between the concentration or input amount of the target substances and the product aspect** under investigation (for product aspect (o), this is done via the link addressed between the LCI and the LCIA). In the proposed simplified broader approach, information on substances used along the life cycle of the product under study may be missing, thus limiting the possibility to perform a full LCA for the analysis of product aspect (o).

164 Mudgal, S., Le Guern, Y., Tinetti, B., Chanoine, A., Pahal, S., Witte, F., Comparative Life-Cycle Assessment of nickel-cadmium (NiCd) batteries used in Cordless Power Tools (CPTs) vs. their alternatives nickel-metal hydride (NiMH) and lithium-ion (Li-ion) batteries, 2011, BIO, https://ec.europa.eu/environment/pdf/waste/batteries/report_12.pdf.

- **<u>Step 4</u>**: Determine the **limit value** that has a significant contribution of the substances to the product aspects under investigation, on the basis of the evidence gathered from stakeholders, literature regarding defined amounts/concentrations of substances that produce negative effects on product aspects and environmental footprint results, the technical feasibility of which has been assessed in the Preparatory Study.
- **<u>Step 5</u>**: Whenever a performance requirement proposed on a substance consists of a restriction that could prevent the delivery of its functionality, carry-out an evaluation of alternative substances, in order to determine whether imposing the proposed limitation would be technically feasible, environmentally sound and proportionate from the economic point of view (see Section C2).
- **<u>Step 6</u>**: Where the evaluation of alternatives positively concludes that suitable alternatives exist, propose a **performance requirement** for the target substance.

5.2 C2: Proposed approach for the evaluation of alternatives (preventing regrettable substitution)

The aim of this section is to guide the evaluation of the alternatives when one or more performance requirement(s) might be under consideration in Section C1 for substance(s), and in particular for SoCs, according to ESPR Annex I (f).

The following paragraphs first describe the context of the evaluation of the alternative (hereafter, assessment) and the cases when it is necessary, then the background and the structure of the assessment, focussing on the main elements and the underlying method. Specific examples and reference to existing guidance / frameworks are provided.

5.2.1 Introduction to substitution in the context of the ESPR

In the context of the ESPR, the evaluation of the alternative(s) allows the PS team to verify that suitable alternative(s) exist on the market, where a performance requirement(s) is being considered for a substance (hereafter, target substance) as the outcome of Section C1. As already introduced in Section C1, this assessment is suggested only in the case of where a complete ban is being contemplated, or a maximum concentration threshold, wither of which might prevent the delivery of the functionality of the target substance, along the life cycle stages of the product.

According to Annex II to the ESPR text, which defines the procedure for defining performance requirements:

"Any concentration limit for substances as referred to in Annex I, point (f), shall be based on a thorough analysis of the sustainability of the substances and their identified alternatives, and shall not have significant adverse effects on human health or the environment. Any performance requirement on substances as referred to in Annex I, point (f), shall take into consideration existing chemical safety assessments performed by the relevant Union bodies for the substances concerned, as well as safe and sustainable by design criteria for chemicals and materials developed by the Commission. Proposed concentration limits shall also consider aspects of enforceability, such as analytical detection limits".

According to Annex I (f) of the ESPR, the setting of performance requirements for substances, and in particular for SoCs, (for example: setting of thresholds and /or condition of use for substances in some stages of the product's life cycle), should not only improve the product aspect(s) but, in order to avoid so-called *burden shifting*, should also take in consideration:

- The overall circularity and sustainability aspects related to the performance requirements, while ensuring an acceptable trade-off of functional requirement(s) with the technical/ economic feasibility in implementing the performance requirements (*assessment of performance requirements*); this aspect is partially considered in the outcome of Section C1;

— The alternatives available on the market (*assessment of alternatives*). With specific regard to the alternative(s) available on the market, their preliminary evaluation might be also useful to examine in advance the technical/economic feasibility of the substitution and possible issues related to safety and/or sustainability aspects that could lead to a regrettable substitution; the current Section C2 focuses on this assessment.

Under the REACH authorisation and restriction processes, which drives substitution of chemicals concerned owing to their risks, an analysis of alternatives is carried out to determine the suitability of the possible alternative(s). The suitability concept already includes the requirement that such an alternative needs to be safer, i.e. it results in a lower overall risk pertaining to all chemical hazards when compared to the substance to be substituted.

Furthermore, according to the ECHA Guidance on the preparation of an application for authorisation (ECHA, 2021[165]), an "*alternative (…) should be able to replace the function that the substance performs. The alternative could be another substance, or it could be a technique (e.g. a process, procedure, device, or modification in an end product) or a combination of technical and substance alternative. For example, a technical alternative could be a physical means of achieving the same function of the Annex XIV substance or perhaps changes in the production, process or product that removes the need for the substance function altogether*". Subsequently, a key to identify a suitable alternative is the analysis of the **functional requirements** of the target substance, while the alternative may consist of an alternative substance (**chemical substitution**) or an alternative solution (**functional substitution**) that focus on the function that the substance provides in its end-use. In the latter case, the alternative may entail the use of no (substitute) substances at all, but for example may consist of a re-design of the process, or the use of an alternative technology. Appendix IV of the afore-mentioned ECHA guidance includes specific questions to identify functional requirements. Additional information is available in Tickner et al, 2019[166].

This **functional substitution** approach is also in line with the ECHA Strategy to promote substitution to safer chemicals through innovation (ECHA, 2018[167]), where considerations of the (technical) function of the substance are considered to be key, rather than focusing on substances with a similar chemical structure. As such, a wider range of substitution solutions may be considered, moving away from similar chemical substitutes which may lead to substitution with alternative(s) that have similar hazard and risk profiles.

Regrettable substitution

With regard to safety aspects, regrettable substitution may occur, e.g., when the alternative is a substance (chemical substitution) with a similar (in terms of hazards posed) molecular structure (*drop-in substitution*). In this case, whilst the alternative may provide an acceptable trade-off between technical performance requirements within the technical/economic feasibility assessment (thereby requiring only little or no process or product redesign), such a situation could require future regulatory scrutiny, where the alternative has a similar hazard and risk profile. There are many examples of regrettable substitution where the hazardous properties of the potential alternative substance were proven to also lead into high risks, resulting in necessary subsequent regulatory intervention, for instance the replacement of BPA (Bisphenol A) with BPS (Bisphenol S) and the substitution of PFOA (perfluorooctanoic acid) with PFHxS (perfluorohexane sulphonic acid).

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[165] ECHA, 2021. Guidance on the preparation of an application for authorisation.

[166] Tickner J. A., Schifano J. N., Blake A., Rudisill C. and Mulvihill M. J., 2019. Advancing Safer Alternatives Through Functional Substitution. Environmental science and technologies. https://pubs.acs.org/doi/10.1021/es503328m

[167] ECHA, 2018. Strategy to promote substitution to safer chemicals through innovation.

On the other hand, the concept of regrettable substitution (chemical and functional) occurring as a result of sustainability concerns has to date not been explored to the same extent. Such cases of regrettable substitution may occur where an alternative, which performs better from the point of view of safety, results in a negative trade-off with regard to other environmental impacts, for example regarding the use of energy or water during one of the life-stages of the alternative substance. An example of possible trade-offs is reported in the Best Available Techniques (BAT) Reference Document (BREF) for the Textiles Industry (Roth et al., 2023[168]) regarding the substitution of complexing agents containing phosphorus (e.g. tripolyphosphate) or nitrogen (e.g. polycarboxylic acids such as EDTA or DTPA), which are used in wet processesing (e.g. pretreatment, dyeing and finishing). In this case, the suggested substitute substances were biodegradable / bioeliminable substances, such as phosphonates (e.g. aminotris methylene phosphonic acid (ATMP), diethylenetriamine pentamethylene phosphonic acid (DTPMP) and 1-hydroxyl ethylidene-1,1-diphosphonic acid (HEDP)).

As reported in the Textiles BREF: "*regarding the use of phosphonates (e.g. DTPMP, HEDP) as substitutes, it is to be noted that the majority of phosphonates are not biodegradable, but bioeliminable. Due to the very slow degradation and the small number of phosphonate-utilising species of microorganisms, it is thus assumed that phosphonates cannot be mineralised in conventional biological WWTPs [waste water treatment plant], aerobically or anaerobically. Accordingly, phosphonates remain in adsorbed form in the sewage sludge in their original form and can only be completely oxidised ('mineralised') and thereby removed from the environment by combustion of the sewage sludge*". Consequently, this substitution would result in exchanging the emissions in wastewater of phosphorous and nitrate (resulting from the mineralisation of the target substances) for the impacts of increased energy use, transport and emissions associated with the incineration of sludge. This trade-off might well be unacceptable, depending on the assessment via LCA, etc.

In the context of the present assessment, a regrettable substitution should be understood as the replacement of a target substance with an alternative, either a chemical and/ or functional substitution, resulting from the setting of performance requirements on the target substance, that lead to: *(i)* either a worsening of product sustainability or safety aspects *or (ii)* to an unacceptable trade-off between functionality and technical/economic feasibility or (*iii*) an insufficient improvement of the product aspect associated with the substance-related performance requirement, as proposed.

Other initiatives and frameworks on substitution

The present report takes into account existing and ongoing EU/ international frameworks, as follows:

- Existing EU framework/Guidance dealing with Analysis of Alternatives and Socio-Economic Analysis developed by ECHA in the context of AfA (Application for Authorisation) (ECHA, 2021)[169] or BPR (Biocidal Products Regulation) (ECHA, 2023)[170];

[168] Joze Roth, Benoit Zerger, Damien De Geeter, Jorge Gómez Benavides, Serge Roudier, Best Available Techniques (BAT) Reference Document for the Textiles Industry, Publications Office of the European Union, Luxembourg, 2023, doi:10.2760/355887, JRC 131874.

[169] ECHA, 2021. Guidance on the preparation of an application for authorisation.

[170] ECHA, 2023. Analysis of alternatives to biocidal active substances for applicants and authorities: a recommended framework guidance.

— Existing international frameworks such as the Alternatives assessment and substitution of harmful chemicals developed by OECD (OECD, 2019[171], 2021[172]) and UNEP (UNEP, 2023[173]);

— Outcomes of the action plan under the EU's Chemical Strategy for Sustainability (CSS), including the SSbD (Safe and Sustainable by Design) framework (Caldeira et al., 2022[174]; EC, 2022[175]; Abbate et. al, 2024)[176] and the Common Data Platform on Chemicals (CDPC) (EC, 2023)[177];

— Transition Pathway for the Chemical Industry published in January 2023 (EC, 2023), including the concept of Substitution Centres, which is currently in the early stages of development, aimed at helping all businesses and value chains regarding the systematic substitution of hazardous substances with safer chemicals and non-chemical alternatives;

— Communication on Essential Use criteria (EC, 2024).

5.2.2 Proposed method for identifying and assessing alternatives

The method described in this section takes into account the framework for analysis of alternatives and socio–economic analysis developed by ECHA (2018, 2021, 2023) and OECD (2019, 2021, 2013), and the Safe and Sustainable by Design (SSbD) Framework developed by JRC (Caldeira et al., 2022[178]; EC, 2022, Abbate et al., 2024[179]).

According to the method proposed in this section, i.e., to verify the availability of suitable alternatives on the market, the alternative should first be identified and then evaluated under different aspects, including the technical/economic feasibility of the substitution and the safety and sustainability aspects, to avoid regrettable substitution. According to the outcome of the assessment:

— Where a suitable alternative is not available, the possible performance requirement being considered in C1 cannot be proposed; therefore, it would need to be revised through the reiteration of section C1, or ultimately be discarded (i.e. no performance requirement proposed);

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171 OECD, 2019. Cross Country Analysis: Approaches to Support Alternatives Assessment and Substitution of Chemicals of Concern

172 OECD, 2021. Guidance on Key Considerations for the Identification and Selection of Safer Chemical Alternatives

173 UNEP, 2023. Chemicals in plastics a technical report

174 Caldeira, C., Farcal, R., Moretti, C., Mancini, L., Rauscher, H., Rasmussen, K., Riego, J., & Sala, S. (2022). Safe and Sustainable chemicals by design chemicals and materials: Review of safety and sustainability dimensions, aspects, methods, indicators, and tools. EUR 30991 EN, Publications Office of the European Union, Luxembourg, 2022, ISBN 978-92-76-47560-6, Doi:10.2760/879069, JRC127109, March, 1–185. https://publications.jrc.ec.europa.eu/repository/handle/JRC127109

175 European Commission, 2022. Commission Recommendation (EU) 2022/2510 of 8 December 2022 establishing a European assessment framework for 'safe and sustainable by design' chemicals and materials. EUR-Lex - 32022H2510 - EN - EUR-Lex

176 Abbate, E., Garmendia Aguirre, I., Bracalente, G., Mancini, L., Tosches, D., Rasmussen, K., Bennett, M. J., Rauscher, H., & Sala, S. (2024). Safe and sustainable by design chemicals and materials—methodological guidance. Publications Office of the European Union. https://doi.org/10.2760/28450

177 European Commission, 2023. Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL establishing a common data platform on chemicals, laying down rules to ensure that the data contained in it are findable, accessible, interoperable and reusable and establishing a monitoring and outlook framework for chemicals.

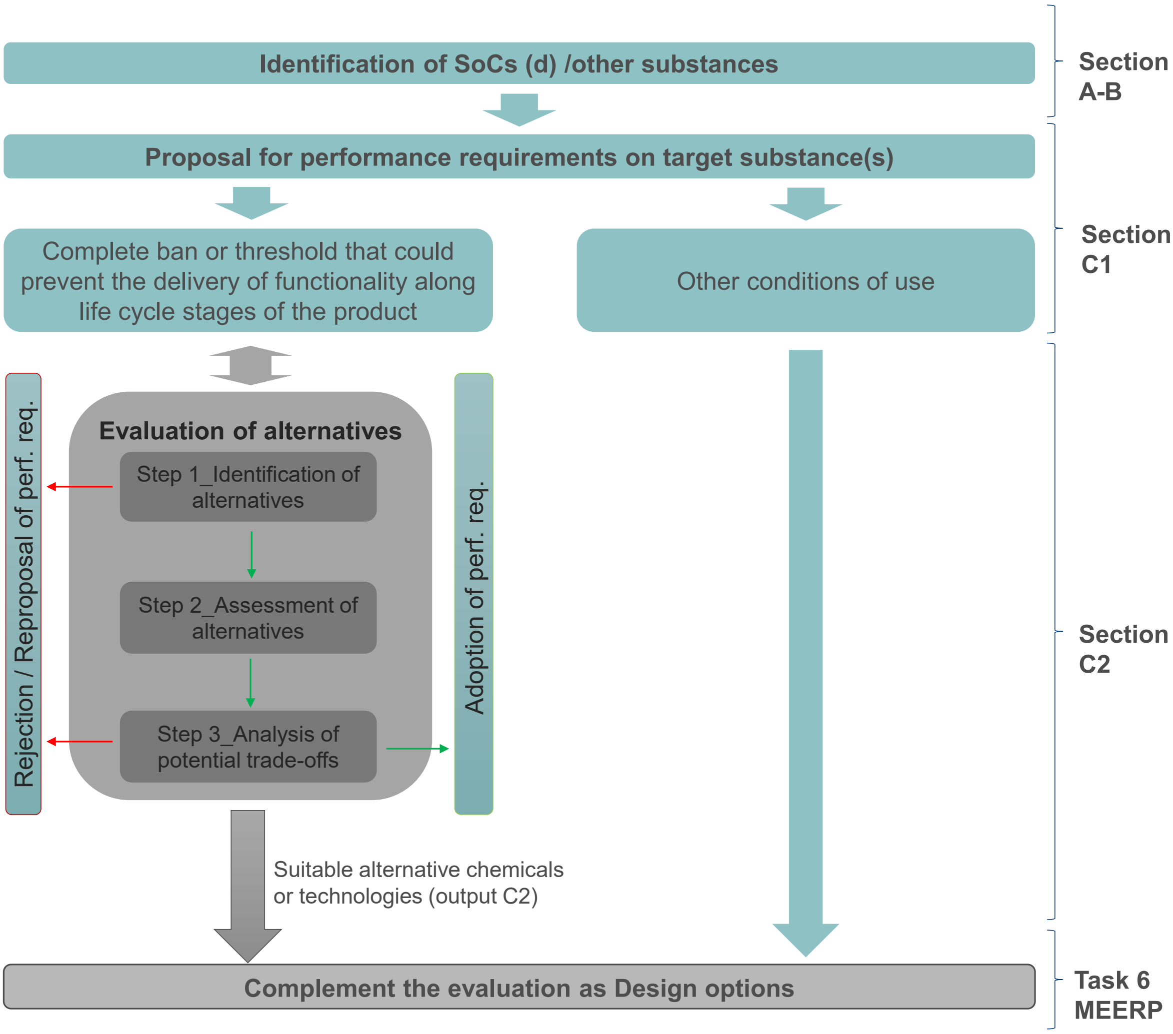
178 Caldeira, C., Farcal, L., Garmendia Aguirre, I. et al., Safe and sustainable by design chemicals and materials – Framework for the definition of criteria and evaluation procedure for chemicals and materials, Publications Office of the European Union, 2022, https://data.europa.eu/doi/10.2760/487955.

179 Abbate, E., Garmendia Aguirre, I., Bracalente, G., Mancini, L., Tosches, D., Rasmussen, K., Bennett, M.J., Rauscher, H. and Sala, S., Safe and Sustainable by Design chemicals and materials - Methodological Guidance, Publications Office of the European Union, Luxembourg, 2024, doi:10.2760/28450, JRC138035.

— Where a suitable alternative **is** available, the performance requirement being considered in C1 can be proposed. In Task 6 "Design options" of the MEErP in the Preparatory Study, the evaluation of the suitable alternative(s) can be further complemented, to take into consideration all the relevant product aspects.

Figure 10 summarises the main elements of the assessment, namely the analysis of alternatives and the method implied, and how these elements are connected with each other. "Adoption" is used in the technical sense (i.e., the proposal is considered to be sound and workable), rather than in the regulatory sense, since the PS team will be supporting the technical evaluation and giving input to possible proposals at this stage.

Figure 10. Structure of the assessment for evaluation of the alternatives and connection with other sections of the ESPR methodology and with the MEErP.



Source: JRC's own elaboration.

The **method** includes a preliminary consideration of data quality, followed by three steps:

— Step 1 → Identification of alternatives (analysis of functionality, technologies and cost)

— Step 2 → Assessment of alternatives (safety and sustainability)

— Step 3 → Analysis of potential trade-offs

Preliminary data quality considerations

The level of investigation of the three steps depends on the availability and quality of data. As a general rule, where there is an absence of data, or limited data availability, the PS team may not be able to perform a meaningful assessment. In such cases, limitations and data gaps should be clearly described in the PS, as well as an indication as to how these limitations could be overcome in the future.

When assessing the availability of data for an evaluation of alternatives, in addition to the information available from public and/or licensed databases, the availability of data from the stakeholders involved in the PS should also be considered. In general, no novel data is expected to be produced during the period of the PS; nevertheless, on a case-by-case basis, and depending on the time and resources available, the possibility to cover an important data gap can be considered, for example by drawing together the strands of evidence in the context of ongoing research and innovation programmes focused on substitution.

A minimum amount of information is necessary to carry out at least a qualitative assessment of the alternative substance. The minimum data requirements may be different, depending if the target substance is a SoC as defined in the ESPR Art. 2(27). Where the identified alternative is defined as a SoC *via* the ESPR Art.2 (27) a, b, c definitions, it is likely that there will be more data available from regulatory processes (e.g., Annex XV from REACH); however, in this case, there is a higher risk that the substance is identified as a possible regrettable (chemical) substitution, and thus not be considered as a suitable candidate alternative for proposing. On the other hand, where the identified alternative does not meet the ESPR Art.2 (27) (a), (b), (c) SoC definition, there might be less data available (especially if the substance is not registered under REACH, its production being below 1 tonne/year). The advantage of the latter candidate alternative substance is that it would normally pose less of a risk of regrettable substitution (chemically), at least regarding the safety aspects.

In the Steps below, a list of possible sources of data is reported, in particular **Table 9** for the Identification of alternatives (Step 1) and **Table 10** and **Table 12** for Safety and sustainability assessment (Step 2).

Step 1 → Identification of alternatives (analysis of functionality, technologies and cost)

Once the performance requirement(s) for a substance has(ve) been proposed (outcome of section C1), the PS team should investigate the market availability of alternatives to ensure that there is no significant reduction in the functionality of the product under study, from the perspective of the user. This involves an analysis of the available technologies and a screening of the economic feasibility of the alternatives (techno-economic analysis). The analysis is aimed at determining whether alternative(s) exist on the market with the same technical function and economic characteristics as the target substance.

At this point, please note that a more comprehensive analysis of costs takes place in Task 6 of the MEErP. Based on the function of the target substance (functions are defined in Section A). The PS team should preliminarily identify the alternatives available in the market with the same function: the same approach provided in Section C1 under *Functional requirements* should be followed. The screening of potential alternatives to the target substance could indeed benefit from the information gathered in the previous sections, where substances having a similar functionality are identified. A non-exhaustive list of sources to screen available alternatives, based on the function of the target substance, is reported in **Table 9**. This first screening should also take into account the quantity of alternative(s) available on the market (also considering the Technology Readiness Level [TRL]). It should be noted that an alternative which is only available at a low TRL, i.e., at R&D or pilot scale, cannot be recommended as a candidate alternative, since it would not be readily available in sufficient quantities in the short-term, as a replacement for the target substance, as well as not yet fully being proven (until reaching higher TRL) at commercial scale.

However, where alternative(s) are currently not available, but a path to substitution has been set within the value chain, including the development of one or more alternatives, **this should be taken into account.** In this latter case, the performance requirements proposed in section C1 could be proposed with specific time-limited exemption(s) or with a defined delayed date for entry into application (similar to the Ecodesign "Tiers" with future-oriented application dates, as used in the numerous "daughter regulations" within the framework of Ecodesign Directive (Energy-related Products) 2009/125/EC).

The preliminarily identified alternatives should be subject to an evaluation of the **technical feasibility of alternatives**. Changes in the manufacturing process of the product and its components may need to be considered to accommodate the potential alternatives. To carry out the evaluation of technical feasibility, associated criteria may need to be developed. This list of criteria may include the tolerances of these requirements (i.e. an acceptable range) and may also include consideration of the constraints on functionality. Where changes in the manufacturing process might be necessary to allow the use of (an) alternative(s), criteria may include the range of conditions that can be achieved with the available technology, and an evaluation of whether the existing technology(ies) enable the alternative(s) to be used for the desired function. The Technology Readiness Level of the alternative(s) should also be considered, i.e. only alternatives readily and widely available in the market should be analysed.

The development of criteria for evaluating technical feasibility could include a series of steps:

- Review the functional requirements of use of the alternatives;
- Identify relevant performance characteristics that could be qualitatively or quantitatively evaluated;
- Establish a performance scale for each of the performance measures to facilitate evaluation of the alternative(s).

For further information, refer to chapter 3.6 of ECHA guidance (ECHA, 2021[180]). The scope and depth of this task in an ESPR Preparatory Study will be determined by the availability of information. As a minimum, the PS study practitioners should strive to provide a qualitative assessment.

The evaluation of the **economic feasibility of alternatives**, should focus on the economic viability of the substitution of the target substance with the alternative(s). The assessment may consider the economic impacts of the (full or partial) transferral to an alternative(s) and the use of an alternative(s) within the supply chain and include:

- The investment and recurrent costs of taking up the alternative(substance(s) or technology(ies), including an assessment of how they may change over time;
- Other costs of transferral to the alternative(s) – including equipment, training, energy use, regulatory compliance costs, potential down-time and handling to the extent that these are not covered under recurrent costs;
- The cost of R&D – including trials;
- The time spent and other costs by downstream users in re-specifying alternative product(s)/ process(es) and, if required, in their re-certification.

[180] ECHA, 2021. Guidance on the preparation of an application for authorisation.

For further information, refer to chapter 3.8 of ECHA guidance (ECHA, 2021). The scope and depth of this task in a Preparatory Study will be determined by the availability of information. As a minimum, the PS study practitioners should strive to provide a qualitative assessment.

The **trade-offs** between technical/economic feasibility and the functional requirements also need to be considered. It is suggested that the Preparatory Study team analyses - and consults with stakeholders - the acceptability of the resulting functional performance to the users of the product, as indicated in Article 5(11) of the ESPR. If suitable alternatives are identified for the target substance, the Preparatory Study team should proceed to the next step. However, if the analysis suggests that **no suitable alternatives can be identified**, then the potential ESPR performance requirement for the substance in the form of a ban or limitation that would prevent the delivery of the required functionality of the substance **cannot be proposed**. If this is the case, this conclusion should be clearly flagged in the study report and no additional analysis would be needed.

It should be noted that, in the context of the ESPR, a regrettable substitution might also occur where an alternative does not result in a sufficiently acceptable improvement of the product aspect for which a performance requirement relative to the target substance was proposed. Another example of regrettable substitution would be where the improvement in the product aspect actually brings about an unacceptable trade-off with other product aspects. Whereas this aspect is only partially covered in the present section (specifically in Step 2, with regard to the environmental footprint), it is suggested to take this into consideration for all possible evidence concerning information on negative trade-offs for all relevant product aspects. If the evidence is already reasonably convincing after these further initial screening considerations, they should be reported as such, with the associated level of uncertainty. At this point, the alternative(s) need not be further assessed by the Preparatory Study team.

Step 2 → Assessment of alternatives (safety and sustainability)

Where it is possible to identify suitable alternatives via the previous Step 1 (Identification of alternatives), the Preparatory Study team should analyse the **safety and sustainability** aspects related to the substitution of target substance(s) with the identified alternatives. Whereas the comparison of the safety and sustainability aspects between the target substance and the alternative substance (providing the same functionality) might prove to be easier, the comparison could be more complicated in the case of a functional substitution, specifically where the function related to the target substance is provided by other means than by chemicals.

<u>Safety aspects</u>

The potential alternative(s) identified for the target substance(s), should be evaluated for their **safety aspects**. Also in this case, any other implication related to the substitution, for example the use of different auxiliary or functional chemicals, should be mapped and considered, as well as potential breakdown products.

In the context of the present guidance, the safety aspects related to the potential alternatives should be first evaluated considering if the substance is included in the "Candidate list" of SVHCs (SoCa) or in relevant restriction lists (such as REACH, POP; BPR). **As a general principle, the alternatives listed in specific restriction lists, that is, as relevant to the use of the substance in the product category, should <u>not</u> be selected**.

For those alternatives under scrutiny due to being in a specific regulatory "watch-list" list, e.g. Community rolling action plan (CoRAP) or the Commission's "restrictions roadmap", indicating potential future regulatory limitations, careful consideration should be given to the technical and economic implications of the possible need for further substitution, even if a reduction in hazards or risks is achieved. Additionally, where the target substance is a process chemical, the presence of the alternative in other regulatory lists, such as in occupational and industrial emission legislation, could be considered. **Table 10** provides an example of criteria based on regulatory limitations.

Table 10. Example of evaluation based on regulatory lists.

Criterion	Regulatory limitations (not exhaustive list)	Evaluation
Presence in regulatory lists in EU	Presence of the substance in regulatory list such as: - REACH Restriction (Annex XVII – if relevant to the product); - REACH Authorization (Annex XIV) - POP Restriction (Annex I-IV) – SoC (c) definition under the ESPR - REACH Candidate List (CL) – SoC (a) definition of the ESPR	Red flag
Scrutiny/proposal for inclusion in regulatory lists in EU	Substance under evaluation or proposed for the inclusion in the above-mentioned lists developed under the REACH Regulation and maintained by ECHA: - Registry of Intention (ROI) for restriction, SVHC identification - CoRAP	Potential red flag
Other regulatory lists (for substances not ending in the product)	— Substances included in other regulatory lists, related to: - Occupational hygiene legislation - Industrial Emissions legislation	Further evaluation needed

Source: JRC's own elaboration.

The evaluation of safety aspects should also focus on the hazard properties of the alternative according to the CLP classification (either harmonised classification in Annex VI to CLP, or, if not available, based on leading self-classifications in the C&L database). To rank the alternative's hazard profile against the target substance, or to compare different alternatives, the H criterion proposed in *Hazard assessment* (Step 1) of the SSbD can be used as a reference. SoCs (a) and (b) under the ESPR are covered by the criterion H1-H2. Moving from H1 to H3, a traffic-light approach is suggested to qualify the hazardous profile of the alternative, adapting the approach used in the application of SSbD framework to case studies (Caldeira et al., 2023[181]).

In the case of a chemical substitution, the alternative substance might be available as component of a mixture. Where data on concentration levels of the different component are not available, it is suggested to limit the evaluation of hazardous properties to the alternative substance, rather than considering those relevant to the whole mixture.

A hazard-based evaluation offers a partial information of the safety profile of the alternative. For this reason, the chemical risk profile of the alternative should be taken into consideration, to the extent possible. It should be emphasised that under the ESPR, the PS is not intended to include the carrying out by the PS team of a complete chemical risk assessment for the alternative under evaluation. However, if useful information on the risks of the alternative is available (for example where information has been produced for REACH Registration [Chemical Safety Assessment] or for different regulatory requirements), the chemical risk for human health (workers and consumers) and for the environment along the life cycle of the alternative can be considered and flagged for the specific scenario(s) related to the product group. In order to provide qualitative considerations about the chemical risk profile of the alternatives against the target substance or to compare the chemical risk of different alternatives, the *Human health and environmental aspects* (Step 2 and Step 3) of the SSbD can be used as a reference. Where quantitative information are available, a traffic light system is also suggested, to qualify the risk profile of the alternative according to the RCR (Risk Characterisation Ratio) for the different CS (Contributing Scenario) considered, in line with the approach proposed in the application of SSbD framework to case studies (Caldeira et al., 2023).

[181] Caldeira, C., Garmendia Aguirre, I., Tosches, D., Mancini, L., Abbate, E., Farcal, L., Lipsa, D., Rasmussen, K., Rauscher, H., Riego Sintes, J., & Sala, S. (2023). Safe and Sustainable by Design chemicals and materials - Application of the SSbD framework to case studies. Publications Office of the European Union, Luxembourg, 2023, JRC131878. https://publications.jrc.ec.europa.eu/repository/handle/JRC131878

Table 11 below provides a summary of the hazard- and risk-based criteria and the possible scoring system that may be applied to evaluate the safety profile of the alternative.

Table 11. Example scoring system to evaluation the safety profile of the alternative.

Example of hazard based criteria (according to CLP)	Scorecard
Criterion H1 Human Health — **Carcinogenicity Cat. 1A and 1B** — **Germ cell mutagenicity Cat. 1A and 1B** — **Reproductive / developmental toxicity Cat. 1A and 1B** — **Endocrine disruption Cat. 1 (human health)** — **Respiratory sensitisation Cat 1** — **Specific target organ toxicity - repeated exposure (STOT-RE) Cat. 1, including immunotoxicity and neurotoxicity** Environmental Health — **Persistent, bioaccumulative and toxic / very persistent and very bioaccumulative (PBT/vPvB)** — **Persistent, mobile and toxic / very persistent and mobile (PMT/vPvM)** — **Endocrine disruption Cat. 1 (environment)**	worst
Criterion H2 Human Health — **Skin sensitisation Cat 1** — **Carcinogenicity Cat. 2** — **Germ cell mutagenicity Cat. 2** — **Reproductive / developmental toxicity Cat. 2** — **Specific target organ toxicity - repeated exposure (STOT-RE) Cat. 2** — **Specific target organ toxicity - single exposure (STOT-SE) Cat. 1 and 2** — **Endocrine disruption Cat. 2 (human health)** Environmental Health — **Hazardous for the ozone layer** — **Chronic environmental toxicity (chronic aquatic toxicity)** — **Endocrine disruption Cat. 2 (environment)**	

Example of hazard based criteria (according to CLP)	Scorecard
Criterion H3 Human Health — **Acute toxicity** — **Skin corrosion** — **Skin irritation** — **Serious eye damage/eye irritation** — **Aspiration hazard (Cat. 1)** — **Specific target organ toxicity - single exposure (STOT-SE) Cat. 3** Environmental Health — **Acute environmental toxicity (acute aquatic toxicity)** Physical — **Explosives** — **Flammable gases, liquids and solids** — **Aerosols** — **Oxidising gases, liquids, solids** — **Gases under pressure** — **Self-reactive** — **Pyrophoric liquids, solid** — **Self-heating** — **In contact with water emits flammable gas** — **Organic peroxides** — **Corrosivity** — **Desensitised explosives**	
No criteria No hazard properties	best

Criteria	Example of risk-based criteria	Scorecard
For each contributing scenario, if total RCR < 1		worst
For each contributing scenario, If total RCR>1 but all individual RCRs<1		
For each contributing scenario, If total RCR>1 but at least 1 individual RCRs>1		
For each contributing scenario, If total RCR>1 and more than one individual RCRs>1		best

Source: adapted from Table 3 of Caldeira et al., 2022 and Table 12 of Caldeira et al, 2023.

Table 12 in next page provides an overview of sources of information to assess the hazard properties.

Table 12. Example of sources of information on hazards.

Source	Description	Minimum data requirements
ECHA	ECHA CHEM[182]: makes available information from all REACH registrations received by ECHA EUCLEF[183]: is a tool for regulatory information on chemicals regulated in the EU and what legal obligations are associated to them. EUCLEF includes 51 European legislations., including REACH CL, Annex XIV and Annex XVII, CLP Annex VI, BPR Annex I, POP Regulation Annex I	SoC (d) and other substances: CLP classification of the alternative(s)
OECD	OECD – eChemPortal: provides free public access to information on chemical properties and direct links to collections of information prepared for government chemical programmes at national, regional, and international levels. Access to information on existing chemicals, new industrial chemicals, pesticides and biocides is provide	

Source: JRC's own elaboration.

In the case of a functional substitution, where the functionality provided by the target substance is achieved by other means than its replacement by a chemical alternative, such as via a technology type, the assessment described above may not be fully applicable or even required. Nevertheless, the PS team should investigate whether the alternative technology involves substances that might be emitted during the process or could remain in the final product. In this case, the assessment described above could be fully applied.

Sustainability aspects

In the context of the present assessment, the evaluation of **sustainability aspects** of alternative(s) under consideration should start by considering the overall single score (Environmental Footprint method), and its breakdown into the constituent 16 impact categories, per LCA stage and process, etc. These will already have been identified in the EF method in the LCA analysis performed, as part of **Task 5 of the MEErP,** and include aspects such as climate change, water pollution, water consumption, etc. The possibility of carrying out this assessment will depend on the suitability and the sensitivity of the LCA model to determine the impact of a single substance and on the availability of applicable datasets containing the relevant substances, with their corresponding characterisation factors.

The improvement can be considered acceptable if the environmental impact (both mid-point and end-point up to single score) is lower or equal to the Base Case. More specifically, the identified alternatives should be evaluated to verify that there is an improvement for the product aspects considered, comparing the alternatives with the target substance, without worsening the other product aspects (following the same approach of Section C1). When comparing the environmental impact of the Base Case, the inventory of substances should reflect the different composition, via the inclusion of the alternative(s) substance(s). If possible, the BoM should include the impact that the alternative may have on other substances used, i.e. it should include the use of different functional chemicals and auxiliaries, where that is the case. In the case of a functional substitution, a new Design Option should be built, to consider the different structure of the product (including a new chemical composition) and/ or the different underlying technology(ies).

From the LCA assessment point of view, and without prejudice to the advice provided above, the improvement can be considered acceptable, and the candidate potential performance requirements

182 https://chem.echa.europa.eu/.
183 https://echa.europa.eu/legislation-finder.

may be proposed, if the total environmental impact (single score) of the alternative is lower or equal to the Base Case.

The *Environmental sustainability assessment* (Step 4) of the SSbD Framework may be used as the reference for this phase. When performing the above analyses, it is important to also report on the qualitative level of "LCA data quality" via typical matrices, etc., and to consider the relative levels of uncertainty of the most relevant LCA indicators identified. Further details are given below regarding some of these considerations.

In the context of the present method, the LCA may be used to evaluate the environmental sustainability aspects related to the performance requirements and to the alternatives, comparing them to the performances of the target substance in the Base Case. Following the approach suggested in Step 4 of the SSbD Framework on "Environmental sustainability assessment", depending on the availability and quality of data along the innovation process, it may be possible to move from a simplified-LCA toward a full-LCA aligned with (P)EF requirements. Also depending on the availability of data, it is possible that the evaluation may need to be limited to the comparison of the characterisation factors (CFs) as a first screening approach, which constitutes a partial assessment (because only the impact related to emissions and resource consumption as elementary flows would be captured). However, as reported in Section C1 in the paragraph dedicated to product aspect letter (o) "environmental footprint and carbon footprint", for what concerns the toxicity impact categories, substances should not be ranked based on their relative contributions to toxicity impacts because of the underpinning uncertainties of the toxicity CFs. Thus, the toxicity result of impact categories should be considered in the aggregated form, encompassing all the contributing substances.

A full LCA could, instead, evaluate the potential impact generated from the substances along the entire life cycle of the Base Case. Whether performing a substance-specific LCA is appropriate in the context of an overall Preparatory Study is a matter to be decided on a case-by-case basis; it depends on the relevance of the substance, and the possible substitution via an alternative substance, and on the overall environmental performance of the product assessed.

When assessing the sustainability aspects, the PEF methodology allows for a score obtained from each of the 16 Impact categories to be added, to obtain a single score. When making the comparative LCA of the suggested alternative substance, for each impact category, a negative score (i.e., a smaller impact compared to the original case) indicates an improvement in the environmental impacts of the alternative(s) comparing to the target substance(s). A lower total score of the alternative comparing the target substance, indicates a lower total environmental impact. The actual scoring should be complemented with the comparison shown in **Table 13** below.

Table 13. Example of scoring system after the comparison between the LCA results for impact categories the alternative and the target substance (Base Case).

Relative difference (%) of total score	Scorecard
No improvement	worst
Improvement 0 - 5%	
Improvement 5% - 20%	
Improvement 20% - 40%	
Improvement > 40%	best

Source: Adapted from Table 8 of Caldeira et al., 2022.

Table 14 below, provides an overview of sources of information for sustainability aspects.

Table 14. Example of sources of information for sustainability aspects.

<table>
<tr><th>Source</th><th>Description</th><th>Minimum data requirements</th></tr>
<tr><td colspan="2">Publicly available database</td><td rowspan="6">SoC (d): Information related to negative effects on recyclability (section C1)

Other substances not identified as SoCs: cradle to grave LCA for chemicals and their ultimate application; Characterisation Factors (CFs) (only to check impact due to emissions and resource consumption as elementary flows). However, as reported in section C1, the CFs for toxicity impact categories should not be used to compare or to rank substances, because of the underlying uncertainty.[184]</td></tr>
<tr><td>Datasets for LCA</td><td>Chemical flows</td></tr>
<tr><td>EF 3.1 method</td><td>Characterisation Factors (CFs)</td></tr>
<tr><td colspan="2">Value chain-based information</td></tr>
<tr><td>Consultation within PS</td><td>Recycling performance</td></tr>
</table>

Source: JRC's own elaboration.

According to the results of the safety and sustainability assessment, only the alternative substances showing a better performance for the safety and sustainability aspects should be considered for assessment via Step 3. It should be noted that in the case of an alternative technology (functional substitution), only the results from the sustainability assessment need to be considered.

Step 3 → Potential trade-offs

"Trade-offs" can be defined as a balancing of two opposing situations or qualities, both of which are desired[185]. An evaluation of alternatives requires balancing numerous decision criteria and evaluating the trade-offs between those criteria[186]. Once the safety and sustainability aspects have been evaluated and under the assumption that the alternative leads to an environmental improvement and is considered acceptable according to the criteria outlined above, the last phase of the method requires the determination of whether the proposed substitution with the alternative(s) results in trade-offs, and whether these can be judged to be acceptable. Without this final evaluation, the outcome of substitution could be a situation where the identified alternative(s) provides an acceptable performance in terms of the functionality, safety and sustainability aspects, but where the substitution of the target substance with the alternative is not feasible from a technical point of view, or that it is not acceptable from a value chain perspective.

Using as a starting point the preliminary technical and economic feasibility screening performed under Step 1, and the safety and sustainability screening carried out in Step 2, the retained alternatives should be compared with the target substance, and with each other (if several alternatives are identified) and the potential trade-offs clearly identified. To the extent possible, the technical, economic and safety/sustainability aspects (including the product aspects) of the trade-offs identified should be described, at least in a qualitative manner. This information will be useful in the overall Task 7 Preparatory Study considerations, and in the subsequent legislative impact assessment phases of policymaking in the formal inputs to the legislative process. The information should provide decision-makers with a good basis upon which to discuss policy choices when

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184 European Platform on LCA. EF3.1 Ecotox Explorer. https://eplca.jrc.ec.europa.eu/ecotox.html.

185 https://dictionary.cambridge.org/dictionary/english/tradeoff.

186 Malloy T.F., et al. 2017. Advancing Alternative Analysis: Integration of Decision Science. Environmental Health Perspectives. 125, (6). Available at: https://doi.org/10.1289/EHP483.

comparing trade-offs, even if only qualitative or semi-quantitative, involving different aspects where a comparison may not be straightforward.

If at least some of the alternatives show a better safety and sustainability profile and result in an acceptable trade off (Step 3) compared to the target substance, the potential performance requirement (e.g. the limitation in the use of the target substance) can be provisionally validated and the alternative analysed further in the separate Task 6 of the MEErP.

The trade-offs should be acceptable from the perspective of the whole value-chain, avoiding market disruption (with specific attention to SMEs, where the differences vis-a-vis large companies may be identifiable, again via consultation, where feasible) whilst also ensuring competitiveness of the product sector. Overall, when identifying alternatives considered suitable in the ESPR context, the trade-off(s) should aim to maximise the improvement of safety and sustainability aspects, while exploring the balance between functional requirements and technical and economic aspects of the substitution. The application of (types of) MCDA (Multi Criteria Decision Analysis) may assist in the decision-making process. MCDA provides analytical results that systematically evaluate the trade-offs, allowing those engaged in deliberation to consider how their preferences and the alternatives' respective performance on different attributes affect the decision[187]. Further information on some aspects of MCDA and its application is available in the SSbD Framework and the SSbD Methodological Guidance.

According to the availability of indicators and criteria, the overall evaluation may also rely on expert judgment as part of the MCDA approach.

At the end of Step 3, all the information related to the potential alternative(s) available on the market, together with the recommendation concerning the overall output of the evaluation, can be summarised as for the following **Table 15**.

Table 15. Summary of the evaluation of the alternative(s).

Target substance	Functional requirements	Alternative(s) identified	Type of evaluation	Technical and economic feasibility	Safety and Sustainability aspects	Acceptable trade off
Include here the identifiers of the target substance, as already described in section C1	Include here a description of the functionality requirements provided by the target substance (either in the process, if process chemicals, or in its end use)	Include here the main features of the identified alternative(s) for which a complete evaluation has been done, specifying if chemical or functional substitution	Describe if the evaluation is qualitative or quantitative and if expert judgment has been applied	Include here the explanation of the technical/economic feasibility of the identified alternative(s);	Include here the outcome from the safety and sustainability assessment	Include here the explanation of acceptance or rejection regarding the trade-offs related to the substitution with the selected alternative(s);

Source: JRC's own elaboration.

[187] Perez O. 2010. Precautionary governance and the limits of scientific knowledge: A democratic framework for regulating nanotechnology. UCLA J Environ Law Policy 28:30–76.

5.3 Summary of Section C

In summary, Section C provides guidance for proposing performance requirements on substances (see **Table 16**).

The main steps to be carried out involve identifying relevant substances for possible performance requirements for the product group under study, the evaluation of alternatives and the proposal of possible performance requirements on these substances.

Table 16. Summary of the method in Task B5 - Section C.

Methodology step	Where?	Required by MEErP?	Any addition in Task B5?
Identification of target substances			
identification of the product aspects relevant for the product group under analysis	Task 4	new (Task B2)	-
identification of the substances affecting the relevant product aspect	Task 5	new (Task B5)	- data collection via literature review and stakeholder consultation - analysis of the relationship between the concentration of target substances and the product aspect under investigation - identify the limit value for the potential restriction
Evaluation of alternatives			
identification and assessment of alternatives	Task 5	new (Task B5)	- identification of alternatives: analysis of functionality, technologies and cost - assessment of alternatives: evaluation of safety and sustainability aspects - analysis of potential trade-offs
Preformance requirements			
proposal of performance requirements	Task 6	new (Task B5)	- takes into account the findings from the steps above

Source: JRC's own elaboration

Box 4. Suggested stakeholder engagement during the steps identified in Section C.

→ In the preliminary stakeholder questionnaire, information should be requested regarding which substances may be relevant as candidates for setting performance requirements (i.e. target substances).

→ In the first stakeholder meeting, where the work on Task 1 of the MEErP and preliminary work on Tasks 2-4 is discussed, the same request above should again be made to stakeholders.

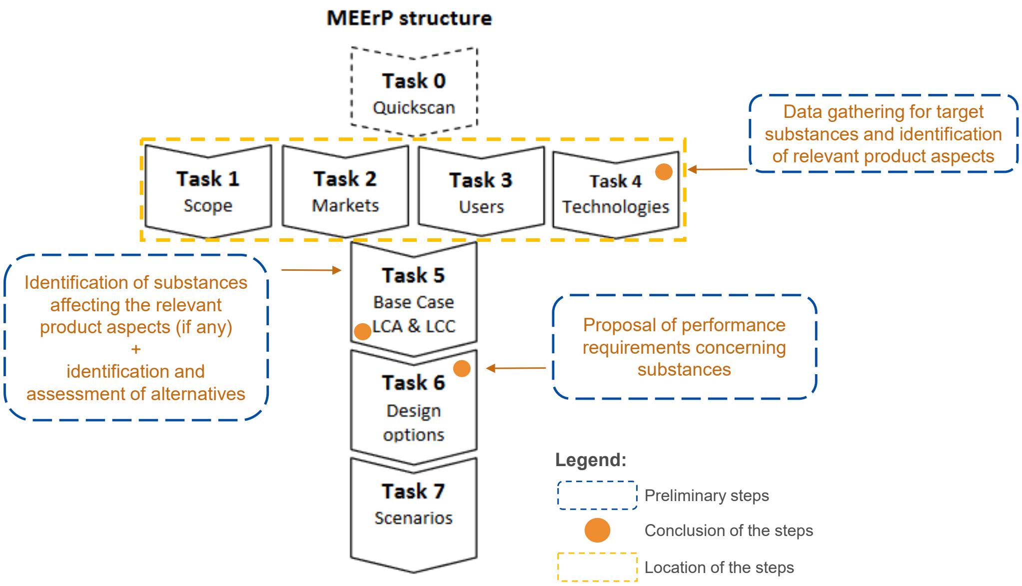
→ In the second stakeholder meeting, where the work on Tasks 2-4 of the MEErP is discussed, the PS team should request information on target substances known to have a possible impact on the product aspects identified as relevant for the product group under study.

→ In the last stakeholder meeting, where the work on Tasks 5-7 of the MEErP is discussed, the PS team should present the target substances identified, if this has been possible, together with the results of the evaluation of alternatives, and the proposal for candidate performance requirements related to such substances. The input from stakeholders should be sought on the proposals made.

→ In addition, as appropriate, targeted sub-groups and bilateral meetings with relevant stakeholders could be organised at any moment during the development of the Preparatory Study.

Similarly, specific surveys could be developed and shared with relevant stakeholders for the request of information on target substances.

Figure 11. Overview of the steps to propose performance requirements concerning substances within the MEErP.

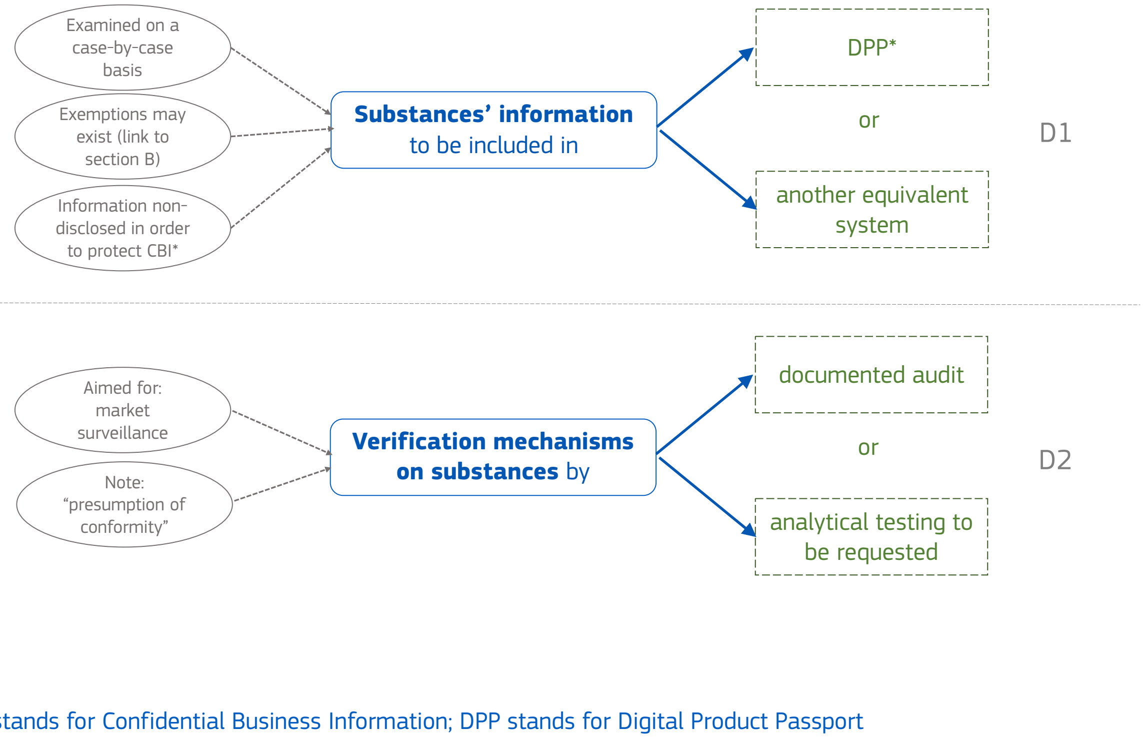


Source: JRC's own elaboration.

6 Section D: Verification of product requirements on the presence of substances

This section aims to identify the information and/or exemptions to be included in the Digital Product Passport and/or other related systems (e.g. EPREL[188] for energy-related products) in relation to substances (section D1); and to discuss the appropriate verification mechanisms for the information and performance requirements in relation to substances (section D2).

Figure 12. Summary of the structure in Section D.



Source: JRC's own elaboration.

6.1 D1: Information concerning substances to be included in the Digital Product Passport or another related system

Section B3 of the current methodology ("Defining information requirements for SoCs under Art. 2(27)") explains which information on substances is to be tracked as part of ecodesign information requirements. In that section it is suggested that the Preparatory Study should provide, if possible, an indicative list of product-relevant SoCs covered under Art. 2(27) (a), (b) and (c), to the extent possible, and a list of all substances identified as SoC (d), relevant to the product (mandatory). This is proposed in line with **Article 7(5) (a) – (e) from the ESPR** which details the information to be included for each substance.

Consequently, for all SoCs known to be in products within the scope of a related ESPR delegated act, the economic operator placing the product on the market should include all the following information in the digital product passport, unless specific thresholds or exemptions apply, as defined in the above-referenced ESPR delegated act:

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[188] European Product Registry for Energy Labelling https://eprel.ec.europa.eu/screen/home.

a) the name or numerical code of the substances of concern present in the product;

b) the location of the substances of concern within the product;

c) the concentration, maximum concentration or concentration range of the substances of concern, at the level of the product, its relevant components, or spare parts;

d) relevant instructions for the safe use of the product;

e) information relevant for disassembly, preparation for reuse, reuse, recycling and the environmentally sound management of the product at end-of-life.

Only if generic or specific thresholds or exemptions apply, or if some of the additional grounds for exemption described below apply, could such information requirements for substances be partially or totally waived. This assessment is to be performed by the Preparatory Study team based on information available at the time when carrying out the study, in particular following stakeholder consultation. Information collected will be analysed and a proposal for a set of ecodesign requirements for inclusion in the product-specific delegated act should then be made, where it is deemed appropriate.

Tracking information concerning SoCs should be included in the DPP, when available, as set out by **Art. 7(7)**: "*Information requirements shall indicate the manner in which the required information is to be made available. Where a digital product passport is available, the required information shall be provided therein and shall, where necessary, also be provided in one or more of the following forms:*

(a) on the product itself;

(b) on the product's packaging;

(c) on a label referred to in Article 16;

(d) in a user manual or other documentation accompanying the product;

(e) on a free access website or application.

Recital (33) reads as follows: '[…] the information to be included in the digital product passport should be carefully examined on a **case-by-case basis when preparing product-specific rules**. To optimise access to the resulting data while also protecting intellectual property rights, the digital product passport needs to be designed and implemented in a manner that allows differentiated access to the data in the digital product passport depending on the type of data and the typology of stakeholders […].'

As already indicated, exemptions could also be possible in the case where a digital product passport is still not available due to the lack of appropriate technical specifications. Recital (35) indicates that: '[…] the Commission should be allowed to **exempt product groups from the digital product passport requirements** where technical specifications are not available in relation to the essential requirements for the technical design and operation of the digital product passport. […] Those exemptions should be periodically **reviewed** taking into account further availability of technical specifications.'

Section B3 discussed the possible exemptions to tracking (i.e. the exemptions to setting information requirements which are defined in **Art. 7(6) b** of the ESPR). A summary of the exemptions on information requirements for substances of concern is reported below (for more details refer to Section B3):

— Aspects related to SoCs which are technically unfeasible to verify/manage;

— Lack of relevance of tracking some SoCs and justified and proportionate protection of confidential business information/ interests, where necessary;

— Lack of suitable analytical methods and/or standards to detect and quantify SoCs.

There may be other **justified cases for exemptions** which are not specified in the legal text (reported in Section B3):

- Existence of similar tracking exemptions in other ESPR delegated acts;
- Other sector-specific regulatory exemptions related to information requirements on substances.

Section B3 of this report further discusses the relevance of **protecting confidential business information (CBI)**, which is mentioned in Article 7(6)(b) as well as in **Article 5(10) d**. The Commission is required to take into consideration the protection of confidential business information when defining Ecodesign requirements[189] and this has an impact on the information to be included in the DPP or other related systems. Given that the ESPR text does not provide further indications of what constitutes confidential business information, nor gives details on how to assess the relevance and proportionality of confidentiality requests, additional guidance is required.

The Preparatory Study team should strive to strike a balance between the public interest for disclosure and consumers' right-to-know *versus* the legitimate need to protect the economic interests of businesses, in particular with regard to their intellectual property. See Section B3.

According to **Article 8** on the content of the delegated acts, these should specify several elements, among which is "*(e) where relevant, requirements for the use of digital tools pursuant to Article 39(2)*". The Preliminary Study team should specify the use of DPP or other information carriers (labels, certificates). As far as the provision of the chemicals-relevant information defined in Article 7(5) is concerned, the appropriateness of further providing this information via product labels or additional physical printed supports should be assessed by the Preparatory Study team. Elements to be considered include the current practice by the sector, the target recipients of the information and the technical and economic feasibility of including such information, which could be extensive, into each physical support. As regards labelling requirements, the provisions in Articles 29 and 31 of the CLP Regulation could be taken into consideration. Specific labelling provision in relevant sectorial legislation, such as for instance those in Regulation (EU) 1007/2011 (the "Textiles labelling regulation") should also be considered.

In **Article 36(3) b** it is said that "*The Commission shall specify the manner in which the relevant parts of the technical documentation are to be made available. Where the digital product passport is available, technical documentation shall be made available through it.*"

> In summary, the chemical information to be included in the digital product passport (and potentially in other related systems) is by default that defined in Article 7(5) of the ESPR. A specific assessment **is required when preparing product-specific rules** in order to define possible thresholds or **exemptions** (as explained in Section B), including information that may justifiably not be disclosed in order to protect **confidential business information**.

Which kind of support or other means should be used to track substances?

Some considerations towards the choice of the means (support) to convey the information requirements requested by ESPR should be provided in the Preparatory Study, i.e. indications on whether this should happen via a DPP or another related system (e.g. EPREL or SCIP); Recital (34) states that:

'*Given that other Union law sets information requirements for products and sets up systems to make information available to economic operators and customers, **the Commission should***

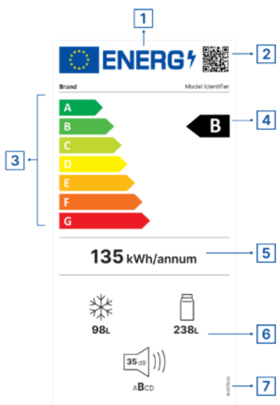
[189] Article 5 (10): '*When preparing ecodesign requirements, the Commission shall ensure consistency with other Union law and shall: [...] (d) take into consideration the protection of confidential business information*';

consider linking information requirements under this Regulation to those other requirements, *such as the obligation to provide safety data sheets for substances and mixtures in accordance with Regulation (EC) No 1907/2006. Where feasible, the Commission should also link the digital product passport to existing Union databases and tools such as the European Product Registry for Energy Labelling (EPREL) or the database for information on Substances of Concern In articles, as such or in complex objects (Products) (SCIP).*'

Considerations regarding **product-related instruments**, which may include information on substances and substances of concern, are provided below.

Defining actual technical approaches and means via which different databases and other data repositories mentioned below could be effectively linked or integrated with the decentralised system defined under the ESPR for the DPP is beyond the scope of the current guidance; however, these issues are of crucial importance in proposing the content of the DPP, and with regard to how some elements may be exempted, due to their prior availability in other systems. The Preparatory Study teams should make their proposals, at the time of drafting said preparatory studies, based on their best understanding of the technical developments of the DPP infrastructure, and of any connections made with other databases and repositories.

EPREL is the **European Product Registry for Energy Labelling**[190], where consumers can find detailed information about energy labelled products and models. It offers the possibility to identify which products have the best energy efficiency and related product-specific and resource consumption, emissions etc information for a specific need. Products included in EPREL are those energy-related products subject to the EU Energy Label, i.e. electronic products such as dishwashers, washing machines, displays or refrigerators.



The EU Energy Label is a language-neutral logo with the word "ENERG", accompanied by a QR code with a link to the EPREL database, the specification of the energy efficiency classes (with a scale from A to G), the energy efficiency class of the product model, the energy consumption, an indication of additional non-energy parameters (noise emissions, water consumption, capacity, repairability or reliability class, etc.) and a reference to the regulation.

Given that the EU Energy Label does not presently include information on substances of concern, this information, as appropriate, would have to be included for such products. It is proposed that under the "additional non-energy parameters" included in energy labelled products, the information is extended with the inclusion of substances of concern that is mandatory under the ESPR.

SCIP[191] is the database for **information on substances of concern** in articles as such, or in complex objects (products) established under the Waste Framework Directive (WFD). It should be noted that in this particular context the reference to **S**ubstances of **C**oncern relates *only* to **substances of very high concern (SVHCs)** in the Candidate List established under the REACH Regulation. At the moment of writing this report, the call for evidence for a measure on "Simplification of administrative burden in environmental legislation" explicitly mentions the possible discontinuation of the SCIP database: '*This may include the following measures:*

190 https://eprel.ec.europa.eu/screen/home
191 https://echa.europa.eu/scip

rationalising reporting/notification obligations, for example, the discontinuation of the SCIP (substances of concern in products) database under the Waste Framework Directive'.[192]

In this regard, companies supplying articles containing substances of very high concern (SVHCs) in the Candidate List in a concentration above 0.1% weight by weight (w/w) on the EU market must submit information on these articles to ECHA, as from 5 January 2021. Building on the provisions of Article 33(1) of REACH, the SCIP database ensures that the information on articles containing Candidate List substances is available throughout the whole life cycle of products and materials, including at the waste stage. The information is contained in a centralised database maintained by ECHA and is made available to waste operators and consumers via a dedicated dissemination portal: https://echa.europa.eu/es/scip-database.

In the case of articles or complex objects (products) included in the SCIP, currently the requested information refers only to SoCs (a). Therefore, these products would need to additionally comply with information requirements for all SoCs including (b), (c) and (d) under the ESPR.

Poison Centres[193]: According to Article 45 of the CLP Regulation, companies placing hazardous mixtures on the market are obliged to provide information about certain hazardous mixtures to the relevant national bodies. The national bodies make this information available to poison centres so that they can give advice to the citizens or medical personnel in the event of an emergency. Annex VIII to the CLP Regulation defines the harmonised requirements for poison centre notifications (PCN), applicable as of 1 January 2021.

Member States must appoint a body or bodies responsible for receiving this information, for formulating preventative and curative measures, in particular in the event of an emergency health response, from importers and downstream users placing mixtures on the market. This information must include the chemical composition of mixtures placed on the market and classified as hazardous on the basis of their health or physical effects, including the chemical identity of substances in mixtures for which a request for use of an alternative chemical name has been accepted. The harmonised **Poison Centres Notification** (PCN) format established by ECHA for submitting the required information to poison centres, available online on ECHA's **Poison Centres website**[194], is an online tool to prepare and submit information according to the harmonised format. ECHA provides three different ways to prepare for the submission of information to poison centres (submissions must adhere to the harmonised PCN format no matter which submission route is used)[195]:

- IUCLID Cloud for users who wish to prepare their notifications online.
- IUCLID 6 using a specific interface[196].
- System-to-system integration for advanced users who wish to automatically generate the data.

Note that PCNs are mostly submitted using the IUCLID system. The dossier may be submitted through the ECHA Submission portal but, as such, is not in included in a publicly available database. Information may only be used as aggregated data for statistical purposes, or to inform risk management analyses. Moreover, ECHA does not own any of the data, since the ownership (and

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192 Simplification of administrative burden in environmental legislation, DG Environment – Unit 01 (Strategy, Digitalisation, Better Regulation and Economic analysis), published 22/07/2025. Available at: https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/14794-Simplification-of-administrative-burdens-in-environmental-legislation-_en

193 https://poisoncentres.echa.europa.eu

194 https://poisoncentres.echa.europa.eu/prepare-and-submit-a-pcn

195 https://poisoncentres.echa.europa.eu/prepare-your-submission

196 https://iuclid6.echa.europa.eu/

databases to search /connect) are the property of the national appointed body which is the final recipient. To summarise, data are only **made available to the relevant Member States' appointed bodies**; hence, it is acknowledged that it will probably be difficult, under the system, that the information linked to PCN can be used by ESPR, and in particular by the DPP.

> As specified in the ESPR text, the **Digital Product Passport and other related systems** are to be used to track information on SoCs. It is suggested that the Preparatory Study team provide the reasoning and a recommendation on the system to be used. Suggestions are provided above for products already included in existing Union databases and tools such as EPREL or SCIP.

6.2 D2: Verification mechanisms for the requirements on substances

Verification is an important element under the ESPR and is particularly relevant from the point of view of **market surveillance**. Both the 2009 Ecodesign Directive (now repealed) and the ESPR work under the concept of "**presumption of conformity**".

Manufacturers or importers of products may only place a product on the EU market when it meets all the applicable requirements, as verified by a conformity assessment procedure that is carried out before the product can be placed on the EU market[197].

A definition for 'conformity assessment' is provided in the ESPR: (51) 'conformity assessment' means the process demonstrating whether the ecodesign requirements set out in the relevant delegated acts adopted pursuant to Article 4 have been fulfilled.

Art 4(5) of the ESPR specifies that the delegated acts shall specify the applicable conformity assessment procedures, from either module A set out in Annex IV to the Regulation or one of the modules B to H1 set out in Annex II to Decision No 768/2008/EC, with the adaptations necessary in view of the product or ecodesign requirements concerned.

Depending on the module specified in the delegated acts, it may be required that the conformity assessment process is carried with the intervention of a notified body, i.e. an organisation 'notified' by a national 'notifying authority' to assess the conformity of certain products and production processes required[198].

The use of harmonised standards remains voluntary, and manufacturers are free to choose another technical solution to demonstrate compliance with the mandatory legal requirements. In such cases, compliance can be demonstrated by referring to technical specifications such as national standards, non-harmonised European and international standards, or companies' technical specifications, providing more details on how the products comply with legal requirements[199].

As also stated in recital (80) of the ESPR: 'Where appropriate, it should be possible for delegated acts setting ecodesign requirements to refer to the use of standards to establish or verify compliance. In order to ensure that there are no barriers to trade on the internal market, such standards should be harmonised at Union level. Once a reference to such standards has been adopted in accordance with Regulation (EU) No 1025/2012 of the European Parliament and of the Council and published in the Official Journal of the European Union, products in conformity with such standards should be considered in conformity with ecodesign requirements adopted pursuant to this Regulation to the extent that they are covered by the relevant harmonised standards. Similarly, methods for tests, measurement or calculation that are in conformity with harmonised standards should be considered in conformity with the requirements for test, measurement and

[197] https://single-market-economy.ec.europa.eu/single-market/goods/building-blocks/conformity-assessment_en.
[198] https://single-market-economy.ec.europa.eu/single-market/goods/building-blocks/notified-bodies_en.
[199] See also the European Union webpage 'Conformity assessment'.

calculation methods set out in the relevant delegated acts laying down ecodesign requirements, to the extent that they are covered by the relevant harmonised standards.'

In order to have a harmonised implementation of the ESPR, it is important that the verification methods and criteria are clear, as it is also stated in ESPR under several articles.

In **Article 5(12) of the ESPR** it is stated that '*Ecodesign requirements shall be verifiable. The Commission shall identify appropriate means of verification for specific ecodesign requirements, including direct checks of the product or on the basis of the technical documentation.*'

Moreover, in Art. 4(6) of the ESPR text it is stated that '*The delegated acts adopted […] may, as appropriate in view of the specificities of the product group, include any of the following additional requirements:*

> *(a) where necessary for effective market surveillance:*
>
> > *(i) that manufacturers, their authorised representatives or importers keep the technical documentation and the EU declaration of conformity for a period other than the 10 years referred to in Article 27(3), Article 28(2), point (a), or Article 29(7), as applicable, after the relevant product has been placed on the market or put into service taking into account the nature of the product or ecodesign requirements concerned;*
> >
> > *(ii) that economic operators provide, upon request, market surveillance authorities with the information set out in Article 36(2), second subparagraph, for a period other than 10 years referred to therein after the relevant product has been supplied;*
> >
> > *(iii) that manufacturers, their authorised representatives or importers make parts of the technical documentation related to the relevant product digitally available to the Commission or market surveillance authorities without a request being necessary, in accordance with Article 36(3);*
> >
> > *(iv) that supply chain actors comply with the obligations listed in Article 38.*'

In **Article 39** of the **ESPR** concerning test, measurement and calculation methods, it is said that (1) '*For the purposes of compliance and verification of compliance with ecodesign requirements, tests, measurements and calculations shall be carried out using harmonised standards or other reliable, accurate and reproducible methods that take into account the generally recognised state-of-the art methods. Such methods shall fulfil the requirements for test, measurement and calculation methods set out in the relevant delegated acts adopted pursuant to Article 4*". Moreover, (2) "*When setting the requirement to use digital tools pursuant to Article 4(6), point (c)(iii), the Commission shall take into account the following criteria:*

(a) the need to ensure the harmonised application of calculation methods; and

(b) the need to minimise the administrative burden imposed on economic operators. Digital tools shall be freely accessible for economic operators."

In some cases, equivalent methods to the harmonised standards may be accepted if they are shown to produce results that can be correlated to results from the cited harmonised standards (when harmonised standards are cited).

Moreover, in **Article 55** related to the application for notification, it is said that (3) "Where the conformity assessment body concerned cannot provide an accreditation certificate, it shall provide the notifying authority with all the documentary evidence necessary for the verification, recognition and regular monitoring of its compliance with the requirements laid down in Article 52.'

According to the above, market surveillance authorities will be required to verify compliance with ecodesign requirements by means of **tests, measurements and calculations using harmonised standards or other reliable, accurate and reproducible methods**, as specified in the delegated act of the specific product.

Therefore, specific tests and methods should be identified and used to verify compliance with information requirements on substance on concern and performance requirements on substances.

As discussed in previous Sections B and C, ESPR delegated acts must provide, where relevant:

- For information requirements:
    - a list of substances of concern under Art. 2(27) (d);
    - applicable thresholds triggering the information requirement for SoCs;
    - a list of exemptions for substances of concern under Art. 2(27) (b), (c) and (d); and
- For performance requirements: a list of substances restricted in the products under the scope of the delegated act.

However, ESPR delegated acts are not required to include a list of substances of concern under Art. 2(27) (a), (b) and (c), given that these are unequivocally identified by the definition reported in Art. 2(27) of the ESPR.

Information on the use and concentration of substances covered by information and performance requirements will be made available by DPP or other related systems, and it is then the responsibility of the economic operator to make sure that the information included in the DPP is complete.

From the side of economic operators, supporting information on the use of substances used in products could be provided by means of **supply chain documentation, third-party audit, analytical test results and/or self-declarations** concerning the data to provide as per Art. 6(2) (performance requirements) and 7(5) (information requirements).

To verify this information, market surveillance authorities are tasked to check:

1. That the information on substances of concern declared in the DPP is correct with respect to, e.g., declared concentrations;
2. That information has not been omitted regarding substances of concern (SoC) in the DPP, i.e. regarding SoC that are used in the product, but which have not been declared; and
3. That no substances are present above the threshold concentration or amount, etc, as specified in the delegated act., subject to **performance requirements** that have been set for the product.

While it should in principle be feasible for market surveillance authorities to verify compliance with points 1 and 3 above, **the verification of the completeness of information (*point 2*) requirements for SoCs under Art. 2(27) (a), (b) and (c) is expected to be a challenge**, given the difficulty in confirming the absence (or absence above a given concentration) of a very large amount of substances potentially present, without knowing in advance those that are explicitly used in the product.

Furthermore, performing targeted tests on substances is complex, due to the potential variability in the results depending on the method used, and there is a potential that such tests may represent a potentially significant economic burden.

To overcome this issue, it is proposed that market surveillance is performed by verifying the information contained in the DPP or another labelling or “carrier” system, together with verifying the supporting information provided by manufacturers via checking the provided documentation, supported by site audits and inspections by third parties as necessary.

Market surveillance authorities may, alternatively or in parallel, carry out targeted **analytical testing** to check or investigate substances for which insufficient information or guarantees are provided by the documentary audits.

For performance requirements, the PS team should provide information on the harmonised or other analytical tests to be used, in order to verify compliance with performance requirements. This includes the setting of verification tolerances[200]. **Article 36(1)** of the ESPR explains which **information obligations** apply to economic operators when putting a product on the market through distance selling, and the information to be provided by companies if requested by market surveillance authorities (Article 36(2)):

> *'1. When making a product covered by a delegated act adopted pursuant to Article 4 available on the market through distance selling, economic operators shall ensure that the product offer clearly and visibly provides at least the following information:*
>
> *(a) the name, registered trade name or registered trade mark of the manufacturer, as well as the postal and electronic address where the manufacturer can be contacted;*
>
> *(b) in the event that the manufacturer is not established in the Union, the name, postal and electronic address and telephone number of the economic operator established in the Union within the meaning of Article 4(2) of Regulation (EU) 2019/1020; and*
>
> *(c) information allowing the identification of the product, including a picture of it, its type and any other product identifier.*
>
> *2. Economic operators shall, upon a reasoned request, provide the market surveillance authorities with:*
>
> *(a) the name of any economic operator that has supplied them with a product falling within the scope of a delegated act adopted pursuant to Article 4;*
>
> *(b) the name of any economic operator to whom or to which they have supplied such products, as well as the quantities and exact models of such products.*
>
> *Economic operators shall ensure that they are able to provide the information referred to in the first subparagraph for 10 years after they have been supplied with the relevant products and for 10 years after they have supplied such products, unless a different period has been specified in the delegated act referred to in paragraph 1. That information shall be provided in paper or electronic form within 15 days of receipt of a request by the market surveillance authority.*
>
> *3. When requiring manufacturers, their authorised representatives or importers to make parts of the technical documentation related to the relevant product digitally available pursuant to Article 4(6), point (a)(iii), the Commission shall take into account the following criteria:*
>
> *(a) the need to facilitate the verification by market surveillance authorities of compliance of manufacturers, their authorised representatives and importers with the applicable requirements; and*
>
> *(b) the need to avoid a disproportionate administrative burden for economic operators, in particular for SMEs.*

[200] The verification tolerances are designed to allow for variations that emerge in the measurements taken during verification tests, which are due to the differences in the measurement equipment used by manufacturers, importers and surveillance authorities across the Union. Verification tolerances should not be used by the manufacturer or importer for establishing the values in the technical documentation or for interpreting those values in order to achieve compliance with ecodesign rules or to communicate better performance than has actually been measured and calculated. The parameters declared or published by the manufacturer or importer should not be more favourable for the manufacturer or importer than the values contained in the technical documentation. (Commission Regulation 2016/2282).

The Commission shall specify the manner in which the relevant parts of the technical documentation are to be made available. Where the digital product passport is available, technical documentation shall be made available through it.'

If there are no other specifications, economic operators should be able to provide the information set out in Article 36(2), second subparagraph, for a **period of 10 years** referred to after the relevant product was supplied.

Article 37 of the ESPR explains which monitoring and reporting obligations exist to economic operators, i.e.:

"*1. When requiring manufacturers, their authorised representatives or importers to make available to the Commission information on the quantities of a product pursuant to Article 4(6), point (b), the Commission shall take into account the following criteria*:

(a) the availability of evidence concerning the market penetration of the relevant product and which is necessary to facilitate the review of delegated acts adopted pursuant to Article 4 applicable to that product;

(b) the need to avoid a disproportionate administrative burden for economic operators, in particular for SMEs; and

(c) the usefulness of the information required and the proportionality of that requirement.

The Commission shall specify the period to which the information referred to in the first subparagraph is to relate. That information shall be differentiated per product model.

The Commission shall specify the means through which the relevant information is to be made available and how frequently such information is to be made available.

The Commission shall ensure that the information made available is processed securely and in compliance with Union law.

2. When requiring that a product be able to measure the energy it consumes or its performance in relation to other relevant product parameters referred to in Annex I while in use, pursuant to Article 4(6), point (c)(i), the Commission shall take into account the following criteria:

(a) the usefulness of in-use data for end users to understand and manage the energy use or performance of the product;

(b) the technical feasibility of recording in-use data;

(c) the need to avoid a disproportionate administrative burden for economic operators, in particular for SMEs; and

(d) the need to ensure that no data allowing the identification of individuals or allowing the inference of individuals' behaviour are collected.

3. Products covered by a requirement set pursuant to Article 4(6), point (c), shall where appropriate, in line with the criteria in paragraph 2 of this Article, record the in-use data and make such data visible to the end user.

4. When requiring manufacturers, their authorised representatives or importers to collect non-personal in-use data referred to in paragraph 2 of this Article and report such data to the Commission, pursuant to Article 4(6), point (c)(ii), the Commission shall take into account the following criteria:

(a) the usefulness of non-personal in-use data for the Commission when reviewing ecodesign requirements or assisting market surveillance authorities with statistical information for their risk-based analysis; and

(b) the need to avoid a disproportionate administrative burden for economic operators, in particular for SMEs.

5. The requirements referred to in paragraph 4 may in particular consist of:

(a) collecting non-personal in-use data if they can be accessed remotely via the internet, following explicit consent being given by the end user to make those data available; and

(b) reporting those data to the Commission at least once a year.

Where reporting is required pursuant to point (b) of the first subparagraph, those data shall include, where available, the identification number of the model as registered in the product database referred to in Article 12(1) of Regulation (EU) 2017/1369 and, if relevant to their performance, general geographical information on the products.

6. The Commission shall specify, in the relevant delegated act, the details and format for reporting the non-personal in-use data as referred to in paragraph 4.

7. The Commission shall periodically assess the non-personal in-use data received pursuant to paragraph 4 and shall, where appropriate, publish aggregated datasets."

ESPR Article 38 sets out the requirements on supply chain actors, when the specific delegated act requests such information:

"*When specified in the delegated act adopted pursuant Article 4, supply chain actors shall*:

(a) provide, upon request and free of charge, manufacturers, notified bodies and competent national authorities with available relevant information related to the products they supply or the services they provide;

(b) allow, in the absence of information referred to in point (a), manufacturers to assess the products they supply or the services they provide and give access to relevant documents or facilities to those manufacturers; and

(c) enable notified bodies and competent national authorities to verify the accuracy of relevant information related to their activities."

Existing examples of ecodesign requirements on substances

Historically, Implementing Acts adopted within the framework of the 2009 **Ecodesign Directive** (now repealed) have focused on energy and resource use during the use stage. More recently, Ecodesign requirements have been established also with respect to material efficiency aspects, such as requirements on spare parts availability, design for recyclability and design for reliability. However, substances (and in particular, substances of concern) have not been the main focus of performance requirements so far, but have figured in mandatory information requirements, particularly regarding the presence of substances in specific components, to enable their rapid identification and removal for separate recycling processes or reuse.

An example of Ecodesign requirements in force on substances lies in Commission Regulation (EU) 2019/2021[201] on **electronic displays**. Annex II, part D, point 3 of that Regulation covers information requirements on cadmium, while point 4 covers performance requirements on halogenated flame retardants.

[201] Commission Regulation (EU) 2019/2021 of 1 October 2019 laying down ecodesign requirements for electronic displays pursuant to Directive 2009/125/EC of the European Parliament and of the Council, amending Commission Regulation (EC) No 1275/2008 and repealing Commission Regulation (EC) No 642/2009, OJ L 315, 5.12.2019, p. 241–266.

Cadmium

Annex II, part D, point 3 to Commission Regulation (EU) 2019/2021 on electronic displays establishes that "*Electronic displays with a screen panel in which concentration values of Cadmium (Cd) by weight in homogeneous materials exceed 0,01 % as defined in Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment, shall be labelled with the 'Cadmium inside' logo. […] A 'Cadmium free' logo shall be used if concentration values of Cadmium (Cd) by weight in any homogeneous material part of the display do not exceed 0,01 % as defined in Directive 2011/65/EU*".

This is an example of existing ***information requirements*** that manufacturers have to make available, in a visible way, so that it is accessible to the user and professional workers handling electronic displays. There is no threshold that triggers the need for the information; i.e., manufacturers always have to inform regarding the presence of cadmium, either with the 'Cadmium inside' or 'Cadmium free' logo. Nevertheless, 0.01% is used as a threshold to distinguish whether the manufacturers need to declare that the screen does or does not contain cadmium in the screen panel. Such a 0.01% threshold refers to the concentration of cadmium in an assumed homogeneous material, which in that Regulation is defined as "*one material of uniform composition throughout or a material consisting of a combination of materials, that cannot be disjointed or separated into different materials by mechanical actions such as unscrewing, cutting, crushing, grinding and abrasive processes*".

Halogenated flame retardants

In the case of Commission Regulation (EU) 2019/2021 on electronic displays, developed under the Ecodesign Directive, market surveillance authorities verify one single unit of the model by means of tests (point 1 to Annex IV to that Regulation). No specific verification method is mentioned in that Annex for the requirements on cadmium and halogenated frame retardants. The pass or fail results of the tests take into account verification tolerances that can be specific to some ecodesign criteria. Such tolerances, set in Table 3 of Annex IV, are not specified for the requirements mentioned above for cadmium and halogenated flame retardants, which suggests that no tolerance is allowed.

Annex II, part D, point 4 to the cited Commission Regulation (EU) 2019/2021 on electronic displays, establishes that "*The use of halogenated flame retardants is not allowed in the enclosure and stand of electronic displays*".

This is an example of a ***performance requirement***, where a restriction is established on a family of substances that are present in a specific part of the product group under the scope of that Regulation, i.e. in the enclosure and stand of the electronic display. With respect to the verification by market surveillance authorities, Annex IV specifies that the requirement on halogenated flame retardants is deemed to be complied with if:

- "*The determined value for HFRs identified in Directive 2011/65/EU does not exceed the relevant maximum concentration values defined in Annex II* to *Directive 2011/65/EU; and*
- *For other HFRs, the determined value for any homogenous material does not exceed 0,1 % by weight of halogen content. Where the determined value for any homogenous material exceeds 0,1 % by weight of halogen content, the model may still be considered compliant where documentary checks or any other appropriate, reproducible methods show that the halogen content is not attributable to flame retardant*".

Modules for conformity assessment procedures

Before products can be placed on the internal market, manufacturers must be able to demonstrate that these products are **safe, and** that they **perform as promised** in terms of safety, reliability, sustainability, energy efficiency and/or other criteria.

Conformity assessment is the name given to the processes used to demonstrate that products, processes, services, persons, systems or bodies meet specific requirements. Typical examples of conformity assessment activities include testing, inspection, certification or accreditation. Conformity assessment may be carried out by a first, second or third party ('SME Guide on Conformity Assessment'[202]).

Conformity assessment must not be confused with **market surveillance**, which consists of controls ***after*** the product has been placed in the market. However, both conformity assessment and market surveillance are complementary tools, and the techniques and procedures used are equally necessary to ensure the smooth functioning of the internal market.

In the context of **Decision 768/2008/EC**, in conformity assessments the legislator requires an "assurance/proof" from manufacturers to ensure their products fulfil the requirements of the legislative instruments that apply to them, prior to their placing on the market[203].

The **assessment of the conformity** of a product is carried out before this product is placed on the market and consists in demonstrating that it fulfils all the legislative requirements that apply to it. The essential objective of a conformity assessment procedure is to demonstrate to public authorities that products placed on the market conforms to the requirements as expressed in the provisions of the relevant legislation, in particular with regard to the health and safety of users and consumers.

Conformity assessment is performed following technical procedures and are composed of **one or two conformity assessment modules**. A conformity assessment procedure covers both **design and production phases**, while a module may cover either one of these two phases (in the case of a conformity assessment procedure that is composed of two modules) or both (in the case of a conformity assessment procedure composed of one module).

As explained by Decision 768/2008/EC, **eight main modules** exist to lay down the responsibilities of the manufacturer and the degree of involvement of an accredited conformity assessment or notified body, in the conformity assessment of a product.

These modules define controls to ensure conformity of a product and the **level of responsibility** at each module and follows procedures that range from **A (internal production control) to H (full quality assurance)**. Some of the modules have variants (e.g. modules A1 and A2). These modules are described more in detail in Decision 768/2008/EC (common framework for the marketing of products).

As explained, specifically, Art. 4(5) of the ESPR provides more details in relation to the conformity assessment procedures and the modules to use either A as in Annex IV to the ESPR or B to H1 of Annex II to Decision No 768/2008/EC.

Art. 4(5): '*In the delegated acts referred to in paragraph 1 of this Article, the Commission shall supplement this Regulation by specifying the applicable conformity assessment procedures from either module A set out in Annex IV to this Regulation or one of the modules B to H1 set out in Annex II to Decision No 768/2008/EC, with the adaptations necessary in view of the product or ecodesign requirements concerned, in accordance with Article 43 of this Regulation.*

Where different conformity assessment modules in Annex II to Decision 768/2008/EC are to be used pursuant to other Union law for the same product, the module provided for in the delegated acts referred to in paragraph 1 shall be used for the ecodesign requirement concerned.

[202] https://sbs-sme.eu/wp-content/uploads/2024/02/SBS-SME-Guide-on-Conformity-Assessment.pdf.

[203] Note, CERTIF 2009–04, on the "Introduction to conformity assessment and conformity assessment procedures of the legal framework (as laid down in 768/2008).

When this Regulation, where appropriate, applies to a product group in a manner complementary to a Regulation of the European Parliament and of the Council laying down harmonised conditions for the marketing of construction products (the 'construction products Regulation'), the delegated act adopted pursuant to paragraph 1 shall specify the conformity assessment procedure, including, where appropriate, any systems provided for pursuant to a measure under the construction products Regulation, taking into account the characteristics of the product group, the relevant ecodesign requirements and the cost for economic operators.'

It is the decision of the legislator to choose the module or combination of modules to be used in relation to a specific product under the ESPR meaning that the PS team or most probably at the delegated act development stage, a decision in relation to the module for conformity assessment would be taken.

The table below summarises **the modules for conformity** as described in the Decision 768/2008/EC and in the 'Blue Guide' on the implementation of EU products rules (2022)[204]. Note this table is a summary that follows the insights set in the 'SME Guide on Conformity Assessment'.

Note that Module A is described in detail in Annex IV to the ESPR where it is explained that (1) 'Internal production control is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 3 and 4, and ensures and declares on its sole responsibility that the product satisfies the requirements of the delegated act adopted pursuant to Article 4'.

Point (2) relates to the 'technical documentation' that the manufacturer should establish consisting of at least: the following elements:

- a general description of the product and of its intended use,
- conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.
- descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the product,
- a list of the harmonised standards, common specifications or other relevant technical specifications the references of which have been published in the Official Journal of the European Union, applied in full or in part, and descriptions of the solutions adopted to meet the requirements where those harmonised standards have not been applied. In the event of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied,
- results of design calculations made, examinations carried out, etc,
- the results of measurements carried out in relation to ecodesign requirements, including details of the conformity of these measurements as compared with the ecodesign requirements set out in the delegated act adopted pursuant to Article 4,
- test reports, and
- a copy of the information provided in accordance with the information requirements pursuant to Article 7'.

Point (3) on manufacturing refers to the necessary measure taken by the manufacturer to 'necessary so that the manufacturing process and its monitoring ensure compliance of the product with the technical documentation referred to in point 2 and with requirements of the delegated act

[204] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52022XC0629(04).

adopted pursuant to Article 4.' Point (4) refers to CE marking and EU declaration of conformity while point (5) relates to the Authorised representative.

Table 17. Modules in conformity assessment.

Module identification	Description	Coverage
A [(1)]	Internal production control	Covers both design and production
A1	Internal production control plus supervised product testing	
A2	Internal production control plus supervised product checks at random intervals	
B	EU-type examination	Covers design
C	Conformity to EU-type based on internal production control	Covers production and follows module B
C1	Conformity to EU-type based on internal production control plus supervised product testing	
C2	Conformity to EU-type based on internal production control plus supervised product checks at random intervals	
D	Conformity to EU-type based on quality assurance of the production process	Covers production and follows module B
D1	Quality assurance of the production process	Covers both design and production
E	Conformity to EU-type based on product quality assurance	Covers production and follows module B
E1	Quality assurance of final product inspection and testing	Covers both design and production
F	Conformity to EU-type based on product verification	Covers production and follows module B
F1	Conformity based on product verification	Covers both design and production
G	Conformity based on unit verification	
H	Conformity based on full quality assurance	
H1	Conformity based on full quality assurance plus design examination	

Source: Decision 768/2008/EC and in the 'Blue Guide' on the implementation of EU products rules (2022), SME Guide on Conformity Assessment.

Note: [(1)] More information in Annex IV to the ESPR.

The **'Blue Guide' on the implementation of EU products rules (2022)** explains in its Section 5.1.9 (Rationale for selecting the appropriate modules) that the legislator should follow a **series of**

principles when selecting modules for a given legislative instrument in relation to the conformity assessment of products. As a general rule, products are subject to both design and production modules before being placed on the market. In general, there are two main principles:

- *The legislator should avoid the setting of modules that are too onerous for the objectives of the Union harmonisation legislation concerned, without however compromising the protection of the public interest.*
- *The complexity of the modules selected should be proportional to the risk (impact on public interest, health, safety, environment) of the product, its design complexity, the nature of its production (large series vs small series, custom-made, simple vs complex production mechanism etc.).*

There are other **eleven principles listed** in the 'Blue Guide', which are as follows:

- *When appropriate in terms of protection of public interest, the manufacturer must be given as wide a choice of modules as possible.*
- *If it is sufficient that the manufacturer carries out himself all checks in order to ensure the conformity of the products, then the legislator may select module A. This can be the case of low complexity (simple design and production mechanism) products that present a low risk for the public interest.*
- *In cases of mass production based on a type/specimen and where the product in question is of complex design or presents higher risks of non-compliance for instance, the EU legislation may lay down the conformity assessment procedure in two steps: first the examination of conformity of the prototype/specimen against the relevant legal requirements (EU-type examination - module B) and then the determination of the conformity of the products against the approved EU-type (modules C and variants, D, E, F).*
- *In cases where the legislator has opted for the demonstration of conformity assessment against a specimen (module B), he must examine the possibility of whether it is sufficient that the manufacturer can carry out himself all checks in order to ensure the conformity in the production phase. If this is the case, then the legislator may select module C.*
- *In many cases the legislator must acknowledge that quite often, manufacturers manage very well equipped testing laboratories or premises. This is usually the case for new innovative complex products for which the testing know-how remains inside the manufacturers. In such cases the legislator may consider selecting either modules A1, A2, or, C1, C2 (the latter two, if he has opted for the demonstration of conformity assessment against a specimen - module B) that allow the use of an accredited in-house body.*
- *If the demonstration of conformity of products against an approved EU-type cannot be left to the manufacturer but requires that products are supervised by a notified body during the production process, then the legislator may require from the manufacturer either to operate an approved quality system (modules D, E) or that the conformity of his products are verified be means of tests/checks (module F). In this respect, if the production mechanism is relatively 'simple' then the legislator may consider that it sufficient that the quality system of the manufacturer focuses only on the test of the final product without including the pure manufacturing part. If this is the case, module E is the most appropriate.*
- *In the case of products of simple design but complicated production/manufacturing, the legislator may consider selecting modules D1, E1, F1 and using thus the advantages of modules D, E and F respectively, without the necessity of recurring to a more formal specimen examination (as provided under module B that precedes modules D, E, F).*
- *For products, produced in small series the legislator may consider selecting module G.*

— *If the manufacturer operates or has to operate a full quality system covering both the design and the production phase, the legislator may opt for module H.*

— *When the manufacturer operates a full quality assurance system, but the verification of the conformity of design and the issuance of EU design examination certificate by a notified body is necessary, then the legislator may select module H1.*

In recital (82) of the ESPR, modules are mentioned, […] '*To ensure consistency with other Union law, the conformity assessment procedures should be chosen from among those of the internal production control module included in this Regulation and of the modules included in Decision No 768/2008/EC of the European Parliament and of the Council*[205]*, ranging from the least stringent to the most stringent*'. […] while in (85), '*Some of the conformity assessment modules laid down in Decision No 768/2008/EC require the intervention of conformity assessment bodies. In order to ensure uniform conditions for the implementation of this Regulation, those bodies should be notified to the Commission by Member State authorities*'.

In **Article 55 of the ESPR**, the application for notification to be done by the conformity assessment body is described:

1. *A conformity assessment body shall submit an application for notification to the notifying authority of the Member State in which it is established.*
2. *That application shall be accompanied by a description of the conformity assessment activities, the conformity assessment module or modules and the product or products for which that body claims to be competent, as well as by an accreditation certificate, where one exists, issued by a national accreditation body attesting that the conformity assessment body fulfils the requirements laid down in Article 52. The accreditation certificate shall relate only to the precise legal body applying for notification and shall be based, in addition to relevant harmonised standards, on the specific requirements and conformity assessment tasks set out in the relevant delegated act adopted pursuant to Article 4.*

Article 56 of the ESPR describes the notification procedure for such conformity assessment which includes the use of an electronic notification tool from the Commission: '*2. Notifying authorities shall notify the Commission and the other Member States using the electronic notification tool developed and managed by the Commission*'.

Article 4(5) of the ESPR, acknowledges that it is at the level of the delegated act when the conformity assessment procedure is to be specified: '*In the delegated acts referred to in paragraph 1 of this Article, the Commission shall supplement this Regulation by specifying the applicable conformity assessment procedures from either module A set out in Annex IV to this Regulation or one of the modules B to H1 set out in Annex II to Decision No 768/2008/EC, with the adaptations necessary in view of the product or ecodesign requirements concerned, in accordance with Article 43 of this Regulation*'.

In the **Final Report** of the "Preparatory study for solar photovoltaic modules, inverters and systems" (2020)[206] a discussion regarding the conformity assessment for solar photovoltaic (PV) modules, inverters, and systems in the context of European Union (EU) regulations is included. Preparatory Study and legislative work began on this product group under the 2009 Ecodesign

[205] Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC (OJ L 218, 13.8.2008, p. 82).

[206] Dodd, N., Espinosa Martinez, M.D.L.N., Van Tichelen, P., Peeters, K. and Soares, A., Preparatory study for solar photovoltaic modules, inverters and systems, EUR 30468 EN, Publications Office of the European Union, Luxembourg, 2020, ISBN 978-92-76-26345-6, doi:10.2760/852637, JRC122431. Available here: https://publications.jrc.ec.europa.eu/repository/handle/JRC122431.

Energy-related Products Directive, showing that the consideration of substances of concern (as well as some being Critical Raw Materials) is not new to Ecodesign legislation.

A summary of the **key points** related to those conformity assessment requirements is provided below:

1. Conformity assessment procedures for PV modules, inverters, and systems are based on the information to that regard used in other EU directives and regulations, such as the Low Voltage Directive (LVD), the Electromagnetic Compatibility (EMC) Directive, and the Construction Products Regulation (CPR).

2. Conformity assessment is usually based on self-certification, followed by factory production control (FPC) and surveillance.

3. For PV systems, conformity assessment is more complex due to the variety of system configurations and components. It suggests that a more comprehensive approach, including inspection and testing of the overall system, may be necessary.

4. The importance of third-party certification is highlighted in ensuring conformity with EU regulations.

5. The need for harmonised standards for PV modules, inverters, and systems to facilitate conformity assessment and ensure a level playing field across the EU is emphasized.

6. Main challenges relate to the need for clearer guidelines, more efficient procedures, and better coordination between EU member states and stakeholders.

The "Preparatory study for solar photovoltaic modules, inverters and systems" discusses **substances used** in solar photovoltaic (PV) modules, inverters, and systems in the context of European Union (EU) regulations and environmental concerns.

1. Substances of Concern (SoCs) identified as used in PV modules and inverters that are considered hazardous or potentially hazardous, include the following:

- Lead (e.g., in soldering and silver paste)
- Cadmium (e.g., in thin-film PV modules)
- Mercury (e.g., in fluorescent lighting used in some PV systems)
- Chromium (e.g., in stainless steel components)
- Cobalt (e.g., in lithium-ion batteries used in some PV systems)

2. RoHS Directive (2011/65/EU) restricts the use of certain hazardous substances in electrical and electronic equipment, including PV modules and inverters.

3. REACH (EC/1907/2006) regulates the use of chemicals in the EU, including those used in PV modules and inverters.

4. Designing PV systems for recyclability and reusability to minimize waste and reduce the environmental impact of substance extraction and processing.

5. Transparency and communication throughout the supply chain are key to ensure that substances used in PV modules and inverters comply with EU regulations and are handled responsibly.

6. Potential future substance-related challenges are the increment of the demand for critical raw materials and concerns about the environmental and health impacts of certain substances (e.g., lead, cadmium).

In the "Commission Staff Working Document Impact Assessment Report" accompanying the "Commission Regulation laying down ecodesign requirements for photovoltaic modules and photovoltaic inverters pursuant to Ecodesign Directive (2009/125/EC) and Commission Delegated Regulation supplementing Regulation (EU) 2017/1369 on energy labelling of photovoltaics modules" (not yet published), requirements on substances are related to material content disclosure, i.e. information requirements. These comprise the declaration of the content (in grammes) and the marking of the location (within components etc.) of certain substances such as cadmium, gallium, indium, lead, silicon metal, silver, tellurium, etc. for recovery, recyclability and/or repairability. Suppliers of solar photovoltaic modules and inverters are required to comply with the REACH regulation (EC) No 1907/2006, but the PV products are exempted from the RoHS Directive 2011/65/EU.

6.3 Summary of Section D

Conformity assessment procedures prior to the placing in the market of products are briefly described to provide some insights aligned with ESPR Annex IV and Decision 768/2008/EC. The summary emphasises on why conformity assessment is needed and its coverage in relation to the responsibilities defined under the different available options.

The **verification mechanisms** for the requirements on substances are to be undertaken by Member States' **market surveillance authorities,** who would need to check the lists of **SoCs (d)**, and if possible **(a), (b), (c)** (information requirements) and substances related to performance requirements (if any) under the delegated act of the specific product.

Market surveillance authorities should be able to seek information and verify compliance using **audit documentation** based on the ecodesign requirements and prepared by manufactures. In addition, further **analytical testing** may be requested by market surveillance authorities if the documentation presented does not fulfil the requirements (using harmonised standards or other accurate methods).

If there are no other specifications, the information for verification should be available for a period of **10 years** after the product's supply.

7 Conclusions

The present report proposes a method for the definition and tracking of substances of concern in products (as defined in Article 2(27) of the ESPR) as well as for the assessment and preparation of restriction measures for substances impacting on the product aspects listed in Article 5(1) of the ESPR.

The suggested method builds upon the existing Methodology for Ecodesign of Energy-related Products (MEErP), which has been used successfully in the framework of the Ecodesign Directive. The method comprises the following main steps:

- a preliminary data gathering phase, resulting in an inventory of substances (to be carried out to the extent feasible), to enable the chemical composition of the product Base Case(s) to be defined;
- the identification of substances of concern that should be subject to information requirements on tracking; and
- where appropriate, the development of considerations for performance requirements on substances occurring in the product or in its life cycle that negatively affect product aspects in Article 5(1), including the evaluation of alternatives to prevent regrettable substitution.

The JRC has provided long-term support to policy DGs in terms of scientific evidence for informing the setting of ecodesign requirements as well as evidence-based research for chemical-related policies. The work presented in this report is part of the scientific support to formulate a methodology for the evaluation of products in the context of the ESPR. It has been performed in synergy with other tasks, collectively contributing to an ESPR methodology. The overall suite of ESPR-related methods will be made available in a combined and integrated format, with the aim of building a comprehensive methodology for practical use by Preparatory Study teams and interested parties in the process, to support the setting of ESPR requirements.

List of abbreviations and definitions

Abbreviations	Definitions
AoA	Analysis of Alternatives
BAT	Best Available Techniques
BP	Best performance product
CAS	Chemical Abstracts Service
CLP	Classification, Labelling and Packaging
CN	Combined Nomenclature
CRM	Critical Raw Material
CTF	Chemicals Task Force
C&L	Classification and Labelling
DSL	Declarable Substance List
DQR	Data Quality Rating
ECHA	European Chemicals Agency
EDC	Endocrine disrupting chemicals
EN	European Norm (standard)
EC	European Commission
EoL	End-of-Life
ErP	Energy-related Products
ESPR	Ecodesign for Sustainable Products Regulation
EU	European Union
GCL	Generic Concentration limit
GHS	Globally Harmonised System

ISO	International Standardisation Organisation
JRC	Joint Research Centre
LCA	Life Cycle Assessment
LCC	Life Cycle Costing
MEErP	Methodology for the Ecodesign of Energy-related Products
POPs	Persistent Organic Pollutants
PS	Preparatory Study
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
SoC	Substance of Concern
SSbD	Safe and Sustainable by Design
SVHC	Substance of Very High Concern

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Annexes

Annex 1. Terminology

Table 18. Definitions related to the product.

Term	Definition	Source
product	product means any physical goods that are placed on the market or put into service	ESPR[5]
component	component means a product intended to be incorporated into another product	ESPR[5]
intermediate product	intermediate product means a product that requires further manufacturing or transformation such as mixing, coating or assembling to make it suitable for end-users	ESPR[5]
energy-related product (ErP)	energy-related product means any product that has an impact on energy consumption during use	ESPR[5]
product group	product group means a set of products that serve similar purposes and are similar in terms of use, or have similar functional properties, and are similar in terms of consumer perception	ESPR[5]
substance	a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition	REACH[207, 208]
mixture	a mixture or solution composed of two or more substances	REACH[207]
article	an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition	REACH[207]
substances which occur in nature	a naturally occurring substance as such, unprocessed or processed only by manual, mechanical or gravitational means, by dissolution in water, by flotation, by extraction with water, by steam	REACH[207]

207 Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC, https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02006R1907-20241218

208 According to the specificities of the product group under assessment, and adapted version of this definition could be considered in each Preparatory study.

Term	Definition	Source
	distillation or by heating solely to remove water, or which is extracted from air by any means	
not chemically modified substance	a substance whose chemical structure remains unchanged, even if it has undergone a chemical process or treatment, or a physical mineralogical transformation, for instance to remove impurities	REACH[207]
polymer	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	REACH[207]
monomer	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 particular process	REACH[207]
alloy	a metallic material, homogenous on a macroscopic scale, consisting of two or more elements so combined that they cannot be readily separated by mechanical means	REACH[207]
substance of concern	substance of concern means a substance that: (a) meets the criteria laid down in Article 57 of Regulation (EC) No 1907/2006 and is identified in accordance with Article 59(1) of that Regulation; (b) is classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 in one of the following hazard classes or hazard categories: *(i) carcinogenicity categories 1 and 2;* *(ii) germ cell mutagenicity categories 1 and 2;* *(iii) reproductive toxicity categories 1 and 2;* *(iv) endocrine disruption for human health categories 1 and 2;* *(v) endocrine disruption for the environment categories 1 and 2;*	ESPR[5]

Term	Definition	Source
	(vi) persistent, mobile and toxic or very persistent, very mobile properties; *(vii) persistent, bioaccumulative and toxic or very persistent, very bioaccumulative properties;* *(viii) respiratory sensitisation category 1;* *(ix) skin sensitisation category 1;* *(x) hazardous to the aquatic environment - categories chronic 1 to 4;* *(xi) hazardous to the ozone layer;* *(xii) specific target organ toxicity – repeated exposure categories 1 and 2;* *(xiii) specific target organ toxicity – single exposure categories 1 and 2;* - (c) is regulated under Regulation (EU) 2019/1021; or (d) negatively affects the reuse and recycling of materials in the product in which it is present;	
unique product identifier	unique product identifier means a unique string of characters for the identification of a product that also enables a web link to the digital product passport	ESPR[5]
unique operator identifier	unique operator identifier means a unique string of characters for the identification of an actor involved in a product's value chain	ESPR[5]
unique facility identifier	unique facility identifier means a unique string of characters for the identification of locations or buildings involved in a product's value chain or used by actors involved in a product's value chain	ESPR[5]
consumer product	consumer product means any product, excluding components and intermediate products, primarily intended for consumers	ESPR[5]
consumer	consumer means any natural person who acts for purposes which are outside that person's trade, business, craft or profession	GPSR (Regulation (EU) 2023/988)[209]

209 Regulation (EU) 2023/988 of the European Parliament and of the Council of 10 May 2023 on general product safety, amending Regulation (EU) No 1025/2012 of the European Parliament and of the Council and Directive (EU) 2020/1828 of the European Parliament and the Council, and repealing Directive 2001/95/EC of the European Parliament and of the Council and Council Directive 87/357/EEC, https://eur-lex.europa.eu/eli/reg/2023/988/oj/eng.

Term	Definition	Source
unsold consumer product	unsold consumer product means any consumer product that has not been sold including surplus stock, excess inventory, overstock and deadstock and products returned by a consumer on the basis of their right of withdrawal in accordance with Article 9 of Directive (EU) 2011/83/EU, or, where applicable, during any longer withdrawal period provided by the trader	ESPR[5]
technical specification	technical specification means a document that prescribes technical requirements to be fulfilled by a product, process or service	ESPR[5]
product presenting a risk	product presenting a risk means a product that, by not complying with a requirement set out in or pursuant to this Regulation other than those listed in Article 71(1), could adversely affect the environment or other public interests protected by that requirement	ESPR[5]
product presenting a serious risk	product presenting a serious risk means a product presenting a risk for which, based on an assessment, the degree of the relevant non-compliance or the associated harm is considered to require rapid intervention by the market surveillance authorities, including cases where the effects of the non-compliance are not immediate	ESPR[5]

Source: JRC's own elaboration.

Additional definitions from non-policy documents:

— 'chemicals':

Collective term covering both substances on their own or in mixtures as defined in REACH and CLP.

— 'material':

According to the 'Mapping study for the development of sustainable-by-design criteria', 'material' denotes either *substances or mixtures which may or may not yet fulfil the definition of an article under REACH and may be of natural or synthetic origin* (EC 2021[210]).

Table 19. Definitions related to the production of the product.

Term	Definition	Source
producer of an article	any natural or legal person who makes or assembles an article within the Community	REACH[207]
manufacturer	manufacturer means any natural or legal person that manufactures a product or that has a product designed	ESPR[5]

[210] Amodio, A., Malyska, A., Markouli, C., et al. European Commission, Directorate-General for Research and Innovation Mapping study for the development of sustainable-by-design criteria, Publications Office, 2021, https://data.europa.eu/doi/10.2777/109081.

Term	Definition	Source
	or manufactured, and markets that product under their name or trademark	
placing on the market	placing on the market means the first making available of a product on the Union market	ESPR[5]
making available on the market	making available on the market means any supply of a product for distribution, consumption or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge	ESPR[5]
putting into service	putting into service means the first use, for its intended purpose, in the Union, of a product	ESPR[5]
importer	importer means any natural or legal person established in the Union that places a product from a third country on the Union market	ESPR[5]
distributor	distributor means any natural or legal person in the supply chain, other than the manufacturer or the importer, that makes a product available on the market	ESPR[5]
actors in the supply chain	actors in the supply chain means all manufacturers and/or importers and/or downstream users in a supply chain	REACH[207]
supplier of a substance or a mixture	supplier of a substance or a mixture means any manufacturer, importer, downstream user or distributor placing on the market a substance, on its own or in a mixture, or a mixture	REACH[207]
supplier of an article	supplier of an article means any producer or importer of an article, distributor or other actor in the supply chain placing an article on the market	REACH[207]
recipient of a substance or a mixture	recipient of a substance or a mixture means a downstream user or a distributor being supplied with a substance or a mixture	REACH[207]
recipient of an article	recipient of an article means an industrial or professional user, or a distributor, being supplied with an article but does not include consumers	REACH[207]
site	site means a single location, in which, if there is more than one manufacturer of (a) substance(s), certain infrastructure and facilities are shared	REACH[207]
identified use	identified use means a use of a substance on its own or in a mixture, or a use of a mixture, that is intended by an actor in the supply chain, including his own use, or that is made known to him in writing by an immediate downstream user	REACH[207]
restriction	restriction means any condition for or prohibition of the manufacture, use or placing on the market	REACH[207]

Term	Definition	Source
supply chain	supply chain means all upstream activities and processes of the product's value chain, up to the point where the product reaches the customer	ESPR[5]
value chain	value chain means all activities and processes that are part of the life cycle of a product, as well as its possible remanufacturing	ESPR[5]
life cycle	life cycle means the consecutive and interlinked stages of a product's life, consisting of raw material acquisition or generation from natural resources, pre-processing, manufacturing, storage, distribution, installation, use, maintenance, repair, upgrading, refurbishment and reuse, and end-of-life	ESPR[5]
destruction	destruction means the intentional damaging or discarding of a product as waste with the exception of discarding for the sole purpose of delivering the discarded product for preparing for reuse, including refurbishment or remanufacturing operations	ESPR[5]
economic operator	economic operator means the manufacturer, the authorised representative, the importer, the distributor, the dealer and the fulfilment service provider	ESPR[5]
CE marking	CE marking means a marking by which the manufacturer indicates that the relevant product is in conformity with the applicable requirements set out in Union harmonisation legislation providing for its affixing	ESPR[5]
provider of an online marketplace	provider of an online marketplace means a provider of an intermediary service using an online interface which allows customers to conclude distance contracts with economic operators for the sale of products covered by delegated acts adopted pursuant to Article 4	ESPR[5]
dealer	dealer means a distributor or any other natural or legal person that offers products for sale, hire or hire purchase, or that displays products, to end users in the course of a commercial activity, including through distance selling; and includes any natural or legal person that puts a product into service in the course of a commercial activity	ESPR[5]

Source: JRC's own elaboration.

Additional definitions from non-policy documents:

— 'process':

According to Safe and Sustainable by Design chemicals and materials - Review of safety and sustainability dimensions, aspects, methods, indicators, and tools, 'process' is operational steps in the manufacturing of a chemical or material (Caldeira et al., 2022[211]).

Table 20. Definitions related to circularity.

Term	Definition	Source
waste	waste means any substance or object which the holder discards or intends or is required to discard	WFD[212] (ESPR is aligned with this definition)
hazardous waste	hazardous waste means waste which displays one or more of the hazardous properties listed in Annex III	WFD[212] (ESPR is aligned with this definition)
waste producer	waste producer means anyone whose activities produce waste (original waste producer) or anyone who carries out pre-processing, mixing or other operations resulting in a change in the nature or composition of this waste	WFD[212]
waste holder	waste holder means the waste producer or the natural or legal person who is in possession of the waste	WFD[212]
broker	broker means any undertaking arranging the recovery or disposal of waste on behalf of others, including such brokers who do not take physical possession of the waste	WFD[212]
waste management	waste management means the collection, transport, recovery (including sorting), and disposal of waste, including the supervision of such operations and the after-care of disposal sites, and including actions taken as a dealer or broker	WFD[212]
waste hierarchy	waste hierarchy means the priority order in waste prevention and management: (i) prevention; (ii) preparing for reuse; (iii) recycling; (iv)	WFD[212]

211 Caldeira C., Farcal R., Moretti C., Mancini L., Rasmussen K., Rauscher H., Riego Sintes J., Sala S. Safe and Sustainable by Design chemicals and materials - Review of safety and sustainability dimensions, aspects, methods, indicators, and tools. EUR 30991 EN, Publications Office of the European Union, Luxembourg, 2022, ISBN 978-92-76-47560-6, doi:10.2760/879069, JRC127109.

212 Waste Framework Directive, Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives (OJ L312, 22.11.2008, p. 3), https://eur-lex.europa.eu/eli/dir/2008/98/oj/eng

Term	Definition	Source
	other recovery (e.g., energy recovery); (v) disposal	
circular economy	circular economy means an economic system in which the value of products, materials and other resources in the economy is maintained for as long as possible, enhancing their efficient use in production and consumption, thereby reducing the environmental impact of their use, minimising waste and the release of hazardous substances at all stages of their life cycle, including through the application of the waste hierarchy	SRS - (EU) 2023/2772[213]
collection	collection means the gathering of waste, including the preliminary sorting and preliminary storage of waste for the purposes of transport to a waste treatment facility	WFD[212]
separate collection	separate collection means the collection where a waste stream is kept separately by type and nature so as to facilitate a specific treatment	WFD[212]
prevention	prevention means measures taken before a substance, material or product has become waste, that reduce: (a) the quantity of waste, including through the reuse of products or the extension of the life span of products; (b) the adverse impacts of the generated waste on the environment and human health; or (c) the content of hazardous substances in materials and products	WFD[212]
reuse	reuse means any operation by which products or components that are not waste are used again for the same purpose for which they were conceived	WFD[212] (ESPR is aligned with this definition)
treatment	treatment means recovery or disposal operations, including preparation prior to recovery or disposal	WFD[212]

[213] Commission Delegated Regulation (EU) 2023/2772 of 31 July 2023 supplementing Directive 2013/34/EU of the European Parliament and of the Council as regards sustainability reporting standards (OJ L, 2023/2772, 22.12.2023) https://eur-lex.europa.eu/eli/reg_del/2023/2772/oj/eng.

Term	Definition	Source
recovery	recovery means any operation the principal result of which is waste serving a useful purpose by replacing other materials which would otherwise have been used to fulfil a particular function, or waste being prepared to fulfil that function, in the plant or in the wider economy. Annex II sets out a non-exhaustive list of recovery operations	WFD[212] (ESPR is aligned with this definition)
material recovery	material recovery means any recovery operation, other than energy recovery and the reprocessing into materials that are to be used as fuels or other means to generate energy. It includes, inter alia, preparing for reuse, recycling and backfilling	WFD[212]
preparing for reuse	preparing for reuse means checking, cleaning or repairing recovery operations, by which products or components of products that have become waste are prepared so that they can be reused without any other pre-processing	WFD[212] (ESPR is aligned with this definition)
recycling	recycling means any recovery operation by which waste materials are reprocessed into products, materials or substances whether for the original or other purposes. It includes the reprocessing of organic material but does not include energy recovery and the reprocessing into materials that are to be used as fuels or for backfilling operations	WFD[212] (ESPR is aligned with this definition)
backfilling	backfilling means any recovery operation where suitable non-hazardous waste is used for purposes of reclamation in excavated areas or for engineering purposes in landscaping. Waste used for backfilling must substitute non-waste materials, be suitable for the aforementioned purposes, and be limited to the amount strictly necessary to achieve those purposes	WFD[212]
disposal	disposal means any operation which is not recovery even where the operation has as a secondary consequence the reclamation of substances or energy.	WFD[212]

Term	Definition	Source
	Annex I sets out a non-exhaustive list of disposal operations	
end-of-life	end-of-life means the life cycle stage that begins when a product is discarded and ends when the waste material of the product is returned to nature or enters another product's life cycle	ESPR[5]
End-of-Waste (EoW) criteria	EoW criteria means the conditions defined to determine that waste which has undergone a recycling or other recovery operation is considered to have ceased to be waste. These include: (a) the substance or object is to be used for specific purposes; (b) a market or demand exists for such a substance or object; (c) the substance or object fulfils the technical requirements for the specific purposes and meets the existing legislation and standards applicable to products; and (d) the use of the substance or object will not lead to overall adverse environmental or human health impacts.	WFD[212]
remanufacturing	remanufacturing means actions through which a new product is produced from objects that are waste, products or components and through which at least one change is made that substantially affects the safety, performance, purpose or type of the product	ESPR[5]
upgrading	upgrading means actions carried out to enhance the functionality, performance, capacity, safety or aesthetics of a product	ESPR[5]
refurbishment	refurbishment means actions carried out to prepare, clean, test, service and, where necessary, repair a product or discarded product in order to restore its performance or functionality within the intended use and range of performance originally conceived at the design stage at the time of the placing of the product on the market	ESPR[5]

Term	Definition	Source
maintenance	maintenance means one or more actions carried out to keep a product in a condition where it is able to fulfil its intended purpose	ESPR[5]
durability	durability means the ability of a product to maintain over time its function and performance under specified conditions of use, maintenance and repair	ESPR[5]
repair	repair means one or more actions carried out to return a defective product or waste to a condition where it fulfils its intended purpose	ESPR[5]
reliability	reliability means the probability that a product functions as required under given conditions for a given duration without an occurrence which results in a primary or secondary function of the product no longer being performed	ESPR[5]

Source: JRC's own elaboration.

Table 21. Definitions related to ecodesign criteria.

Term	Definition	Source
ecodesign	ecodesign means the integration of environmental sustainability considerations into the characteristics of a product and the processes taking place throughout the product's value chain	ESPR[5]
ecodesign requirement	ecodesign requirement means a performance requirement or an information requirement aimed at making a product, including processes taking place throughout the product's value chain, more environmentally sustainable	ESPR[5]
performance requirement	performance requirement means a quantitative or non-quantitative requirement for or in relation to a product to achieve a certain performance level in relation to a product parameter referred to in Annex I	ESPR[5]
information requirement	information requirement means an obligation for a product to be accompanied by information as specified in Article 7(2)	ESPR[5]
environmental impact	environmental impact means any change to the environment, whether adverse or beneficial, wholly or partially resulting from a product during its life cycle	ESPR[5]
environmental footprint	environmental footprint means a quantification of the environmental impacts resulting from a product throughout its life cycle, whether in relation to a single environmental impact category or an aggregated set of impact categories based on the Product Environmental Footprint method	ESPR[5]

Term	Definition	Source
	established by Recommendation (EU) 2021/2279 or other scientific methods developed by international organisations, widely tested in collaboration with different industry sectors and adopted or implemented by the Commission in other Union law	
Product Environmental Footprint method	PEF method means the life cycle assessment method to quantify the environmental impacts of products as established by Commission Recommendation (EU) 2021/2279	Commission Recommendation (EU) 2021/2279[214]
carbon footprint	carbon footprint means the sum of greenhouse gas emissions and greenhouse gas removals in a product system, expressed as CO_2 equivalents and based on a life cycle assessment using the single impact category of climate change	ESPR[5]
biodiversity loss	biodiversity loss means the reduction of any aspect of biological diversity (i.e., diversity at the genetic, species and ecosystem levels) in a particular area through death (including extinction), destruction or physical-manual removal; it can refer to many scales, from global extinctions to population extinctions, resulting in decreased total diversity at the same scale	SRS - (EU) 2023/2772[213]
land degradation	land degradation means the many processes that drive the decline or loss in biodiversity, ecosystem functions or their benefits to people and includes the degradation of all terrestrial ecosystems	SRS - (EU) 2023/2772[213]
planetary boundaries	planetary boundary concept allows to estimate a safe operating space for humanity with respect to the functioning of the Earth. The boundary level for each key Earth System process that should not be transgressed if we are to avoid unacceptable global environmental change, is quantified	SRS - (EU) 2023/2772[213]
class of performance	class of performance means a range of performance levels in relation to one or more product parameters referred to in Annex I, which is established based on a common methodology for the product or product group, ordered in such a way as to allow for product differentiation	ESPR[5]
digital product passport	digital product passport means a set of data specific to a product that includes the information specified in the applicable delegated act adopted pursuant to Article 4 and that is accessible via electronic means through a data carrier in accordance with Chapter III	ESPR[5]

214 Commission Recommendation (EU) 2021/2279 of 15 December 2021 on the use of the Environmental Footprint methods to measure and communicate the life cycle environmental performance of products and organisations (OJ L 471, 30.12.2021, p. 1).

Term	Definition	Source
data carrier	data carrier means a linear bar code symbol, a two-dimensional symbol or other automatic identification data capture medium that can be read by a device	ESPR[5]
self-regulation measure	self-regulation measure means a voluntary agreement or a code of conduct, concluded by economic operators on their own initiative, which they are responsible for enforcing	ESPR[5]
harmonised standard	harmonised standard means a European standard adopted on the basis of a request made by the Commission for the application of Union harmonisation legislation	ES – Regulation (EU) 1025/2012[215] (ESPR is aligned with this definition)

Source: JRC's own elaboration.

Additional definitions from non-policy documents:

— 'safe and sustainable by design'

According to the Chemicals Strategy for Sustainability - Towards a Toxic-Free Environment, chemicals that are 'safe and sustainable by design' is 'a pre-market approach to chemicals and materials that focuses on providing a function (or service), while avoiding volumes and chemical properties that may be harmful to human health or the environment, in particular groups of chemicals likely to be (eco) toxic, persistent, bio-accumulative or mobile. Overall sustainability should be ensured by minimising the environmental footprint of chemicals in particular on climate change, resource use, ecosystems and biodiversity from a life cycle perspective' (EC 2020[216]).

Table 22. Other useful definitions for the purpose of this study.

Term	Definition	Source
complex object	complex object means an object composed of several articles or an object made of two (or more) articles joined or assembled together either: a. mechanically b. using substance(s)/mixture(s) ...	ECHA[217]
complex product	product made of different products/articles but still being an article (Court Judgement C-106/14, 2015)[218]. If the elements could be readily separated, it would be an article or product consisting of several components. The EU Ecolabel Task Force suggests instead	ECHA, Council Regulation (EC) 6/2002[220]

[215] Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the Council (OJ L 316, 14.11.2012, p. 12), https://eur-lex.europa.eu/eli/reg/2012/1025/oj/eng.

[216] Communication COM(2020) 667 Final of 14th October 2020 from the Commission to the European Parliament, the Council, the European Economic and Social Committee and The Committee of the Regions- Chemicals Strategy for Sustainability - Towards a Toxic-Free Environment.

[217] 'Guidance on requirement for substances in articles', available here: https://echa.europa.eu/documents/10162/2324906/articles_en.pdf

[218] Court Judgement C-106/14, 2015. Available here: https://curia.europa.eu/juris/liste.jsf?&num=C-106/14.

[220] Council Regulation (EC) No 6/2002 of 12 December 2001 on Community designs (OJ L 3, 5.1.2002, p. 1). Available at: https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32002R0006.

Term	Definition	Source
	the definition for 'complex article' as: 'An object composed of an assembly of different articles which during production is given a special shape, design, structure and component configuration which determine its function to a greater degree than does its chemical composition or its constituent articles' (JRC, 2014[219]). Alternatively, a complex product is a product which is composed of multiple components which can be replaced permitting disassembly and re-assembly of the product.	
additive	additive means substances added to components, materials or the final product in order to improve or preserve some of its characteristics	EU Ecolabel AHP[221]
impurities	impurities means residuals, pollutants, contaminants etc. from production, including the production of raw materials, that remain in the raw material/ingredient and/or in the chemical product (used in the final product and any component therein) in concentrations less than 100 ppm (0,0100 % w/w, 100 mg/kg)	EU Ecolabel AHP[221]
	impurities means an unintended constituent present in a substance as manufactured. It may originate from the starting materials or be the result of secondary or incomplete reactions during the manufacture process. While it is present in the final substance it was not intentionally added	ECHA[222]
ingoing substance	ingoing substance means all substances included in the chemical product (used in the final product and any component therein), including additives (e.g. preservatives and stabilisers) in the raw materials. Substances known to be released from ingoing substances in stabilized manufacturing conditions (e.g. formaldehyde and arylamine) are also considered as ingoing substances.	EU Ecolabel AHP[221]
non-intentionally added substance	non-intentionally added substance means an impurity in the substances used or a reaction intermediate formed during the production process or a decomposition or reaction product	Commission Regulation 10/2011[223]
registrant	registrant means the manufacturer or the importer of a substance or the producer or importer of an article submitting a registration for a substance	REACH[207]

[219] Dodd, N. and Cordella, M., Kougoulis, J. and Kaps, R. Findings of the EU Ecolabel Chemicals Horizontal Task Force Proposed approach to hazardous substance criteria development, Joint Research Centre, Institute for Prospective Technological Studies (Seville), 2014, https://environment.ec.europa.eu/system/files/2023-02/Chemicals%20HTF_Approach%20paper.pdf

[221] Commission Decision (EU) 2023/1809 of 14 September 2023 establishing the EU Ecolabel criteria for absorbent hygiene products and for reusable menstrual cups (OJ L 234, 22.9.2023, p. 142), https://eur-lex.europa.eu/eli/dec/2023/1809/oj/eng

[222] ECHA guidance document. https://echa.europa.eu/documents/10162/2324906/substance_id_en.pdf/ee696bad-49f6-4fec-b8b7-2c3706113c7d

[223] Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food (OJ L 12, 15.1.2011, p. 1), https://eur-lex.europa.eu/eli/reg/2011/10/oj/eng

Term	Definition	Source
competent authority	competent authority means the authority or authorities or bodies established by the Member States to carry out the obligations arising from this Regulation	REACH[207, 224]

Source: JRC's own elaboration.

[224] Not in ESPR, while included in ESPR: (51) 'conformity assessment' means the process demonstrating whether the ecodesign requirements set out in the relevant delegated acts adopted pursuant to Article 4 have been fulfilled; (52) 'conformity assessment body' means a body that performs conformity assessment activities including calibration, testing, certification and inspection; (53) 'notified body' means a conformity assessment body notified in accordance with Chapter IX.

Annex 2. Regulatory background

Table 23. Summary of legal instruments and other schemes relevant for the purpose of this study.

Legal instruments and other schemes	Short name	Aim	Art. 5(1) aspect(s) addressed	Performance requirements	Information requirements
Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals[225]	REACH	REACH is a comprehensive cornerstone of EU chemicals legislation. REACH Title VIII sets restrictions on chemicals, which shall apply to the manufacture, placing on the market or use of substances on their own, in mixtures or in articles. Manufacturers, importers and downstream users shall ensure that they manufacture, place on the market or use substances in ways that do adversely affect human health or the environment	(g) the presence of substances of concern	Restriction measures for the presence of substances in products, in some cases may include concentration limits	Information requirements for the registration of substances and for communication in the supply chain. Annex II sets requirements for safety data sheets for substances and mixtures
Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures[226]	CLP	CLP sets up a hazards communication scheme for substances and mixtures and serves to ensure the protection of human health and the environment, as well as the free movement of substances, mixtures and articles, it is applicable to substances and mixtures (and to a very limited extent to some articles), and requires manufacturers, importers and downstream users of substances or mixtures to classify, label and package their hazardous substances and mixtures appropriately before placing them on the market	(g) the presence of substances of concern	-	Procedure for hazard classification and labelling; requirements to provide information for the supply chain

[225] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC, Article 57, Article 59(1) (OJ L 396, 30.12.2006, p. 1).

[226] 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 (OJ L 353, 31.12.2008, p. 1).

Legal instruments and other schemes	Short name	Aim	Art. 5(1) aspect(s) addressed	Performance requirements	Information requirements
Regulation (EC) No 66/2010 on the EU Ecolabel[227]	EUEL	Rewarding the excellence of products according to defined chemical safety criteria and environmental process parameters	(a) durability; (b) reliability; (c) reusability; (d) upgradability; (e) repairability; (f) the possibility of maintenance and refurbishment; (g) the presence of substances of concern; (h) energy use and energy efficiency; (i) water use and water efficiency; (j) resource use and resource efficiency; (k) recycled content; (l) the possibility of remanufacturing; (m) recyclability; (n) the possibility of recovery of materials; (o) environmental impacts, including	Criteria and thresholds for aspects in Art. 5(1)	Requirements for information provision for verification and to final consumers

227 Regulation (EC) No 66/2010 of the European Parliament and of the Council of 25 November 2009 on the EU Ecolabel (OJ L 27/1, 30.1.2010).

Legal instruments and other schemes	Short name	Aim	Art. 5(1) aspect(s) addressed	Performance requirements	Information requirements
			carbon and environmental footprint; (p) expected generation of waste		
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products[228]	BPR	The purpose of the BPR is to improve the functioning of the internal market through the harmonisation of the rules on the making available on the market and the use of biocidal products, whilst ensuring a high level of protection of both human and animal health and the environment	(g) the presence of substances of concern	Utilisation of biocidal products (thresholds and restrictions)	Rules for biocides available on the market
Regulation (EU) 2019/1021 on persistent organic pollutants[229]	POPs	Protection of human health and the environment with specific control measures by: (1) prohibiting or severely restricting the production, placing on the market and use of POPs; (2) minimising the environmental release of POPs that are formed as industrial by-products; making sure that stockpiles of restricted POPs are safely managed; and ensuring the environmentally sound disposal of waste consisting of, or contaminated by POPs	(g) the presence of substances of concern;	Restrictions on POPs in production, products and waste	Information such as awareness programmes, the provision of public information, and trainings
Regulation (EU) 2020/852[230]	EU Taxonomy	Establishes a taxonomy to classify a sustainable activities, considering six environmental objectives (climate change mitigation, climate change adaptation, sustainable use and protection of water and marine resources, transition to a circular economy, pollution prevention, control and protection, restoration of biodiversity and ecosystems) with a life-cycle perspective. Basically, it aims to inform investors on whether an	(o) environmental impacts, including carbon and environmental footprint; (p) expected generation of waste	Generic criteria and thresholds regarding use and presence of chemicals (reference to existing regulations, e.g. REACH and CLP). Generic criteria and	Reference to information on and tracking of substances of concern throughout the life cycle of the

[228] Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (OJ L 167, 27.6.2012, p. 1).

[229] Regulation (EU) 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants (OJ L 169, 25.6.2019, p. 45).

[230] Regulation (EU) 2020/852 of the European Parliament and of the Council of 18 June 2020 on the establishment of a framework to facilitate sustainable investment, and amending Regulation (EU) 2019/2088 (OJ L 198, 22.6.2020, p. 13).

Legal instruments and other schemes	Short name	Aim	Art. 5(1) aspect(s) addressed	Performance requirements	Information requirements
		economic activity is environmentally sustainable by setting the mentioned common EU-wide criteria		thresholds (when provided) on greenhouse gas emissions, resource consumption, chemical emissions and chemical content in waste. Generic suggestions for proper waste management (reference to existing regulations)	manufactured products
Regulation (EU) 2023/1542[231]	BATTERIES	Prevent and reduce adverse impacts of batteries on the environment and ensure a safe and sustainable battery value chain for all batteries, taking into account, environmental, social and circularity aspects	(g) the presence of substances of concern; (h) energy use and energy efficiency; (j) resource use and resource efficiency; (k) recycled content; (l) the possibility of remanufacturing; (m) recyclability; (n) the possibility of recovery of materials; (o) environmental impacts, including carbon and environmental footprint; (p)	Safety requirements and restrictions and additional restrictions based on dossier prepared by ECHA at the request of the EC, or by member states, assessing human and environmental risk. The regulation also envisages a mapping of substances of concern in batteries. Sustainability requirements like performance, durability of tools (depending on the device, they could be	Labelling and information requirements. Battery passport.

[231] Regulation (EU) 2023/1542 of the European Parliament and of the Council of 12 July 2023 concerning batteries and waste batteries, amending Directive 2008/98/EC and Regulation (EU) 2019/1020 and repealing Directive 2006/66/EC (OJ L 191, 28.7.2023, p. 1).

Legal instruments and other schemes	Short name	Aim	Art. 5(1) aspect(s) addressed	Performance requirements	Information requirements
			expected generation of waste	defined under appropriate regulations), environmental footprint (e.g. maximum carbon threshold and performance classes, to be defined via delegated act). Circularity requirements like recycled content, recycling and recovery efficiencies	
Regulation (EU) 2023/956[232]	SCF	Meeting the objective of a climate-neutral Union at the latest by 2050 in line with the Paris Agreement by addressing the risk of carbon leakage that results from the Union's increased climate ambition and promote decarbonisation in third countries	(o) environmental impacts, including carbon and environmental footprint	List of goods and greenhouse gases, methods for calculating embedded emissions in simple and complex goods	Minimum data to be kept by an authorised Carbon Border Adjustment Mechanism (CBAM) declarant for imported goods
Regulation (EU) 2023/988[233]	GPSR	Ensure that only safe products are sold on the EU market. It foresees the consumer information of any risks associated with the products, encompassing chemicals concerns not covered by specific regulations, and apply traceability to remove the dangerous products	(g) the presence of substances of concern	General safety (no specific thresholds provided) and product circularity (no specific thresholds provided)	-

[232] Regulation (EU) 2023/955 of the European Parliament and of the Council of 10 May 2023 establishing a Social Climate Fund and amending Regulation (EU) 2021/1060 (OJ L 130, 16.5.2023, p. 1).

[233] Regulation (EU) 2023/988 of the European Parliament and of the Council of 10 May 2023 on general product safety, amending Regulation (EU) No 1025/2012 of the European Parliament and of the Council and Directive (EU) 2020/1828 of the European Parliament and the Council, and repealing Directive 2001/95/EC of the European Parliament and of the Council and Council Directive 87/357/EEC (OJ L 135, 23.05.2023, p. 1).

Legal instruments and other schemes	Short name	Aim	Art. 5(1) aspect(s) addressed	Performance requirements	Information requirements
Directive 2000/60/EC (Water Framework Directive)[234]	Water FD	Ensures water protection in Europe with an integrated approach to water management, respecting the integrity of whole ecosystems, including by regulating individual pollutants and setting corresponding regulatory standards	(o) environmental impacts, including carbon and environmental footprint	List of priority substances to monitor in surface waters, standards listed in Environmental Quality Standards Directive (EQSD) (2022/0344 (COD)). The list of substances and standards for groundwater are set in the Groundwater Directive (GWD) (Directive 2006/118/EC)	-
Directive 2003/87/EC, as amended (EU Emissions Trading System)[235]	EU ETS	Incentivise production from installations that partly reduce or fully eliminate greenhouse gas Emissions with the target of a 55 % reduction of EU net greenhouse gas (GHG) emissions by 2030, compared to 1990 levels	(o) environmental impacts, including carbon and environmental footprint	-	List of activities with thresholds values referred to production capacities or outputs, list of greenhouse gases, calculating formulas of emissions for monitoring and reporting

[234] Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy (OJ L 327, 22.12.2000, p. 1).

[235] Directive 2003/87/EC of the European Parliament and of the Council of 13 October 2003 establishing a system for greenhouse gas emission allowance trading within the Union and amending Council Directive 96/61/EC (OJ L 275 25.10.2003, p. 32).

Legal instruments and other schemes	Short name	Aim	Art. 5(1) aspect(s) addressed	Performance requirements	Information requirements
Directive 2008/98/EC (Waste Framework Directive)[236]	WFD	Protects the environment and human health by preventing or reducing the adverse impacts of the generation and management of waste and by reducing overall impacts of resource use and improving the efficiency of such use	(c) reusability; (k) recycled content; (l) the possibility of remanufacturing; (m) recyclability; (n) the possibility of recovery of materials; (p) expected generation of waste	It sets rules on waste prevention; it sets minimum operating requirements for extended producer-responsibility schemes; it introduces recycling and recovery targets for some waste streams; it promotes the reduction of the content of hazardous substances in materials and products; it stops the generation of marine litter	Waste classification (including hazardous/non-hazardous), waste hierarchy and of end-of-life management operations
Directive 2009/125/EC (Ecodesign of Energy-related Products)[237]	EErPs	Improving the environmental performance of energy-related products (ErPs) by setting mandatory minimum standards for their energy efficiency and, from 2021, their reparability and recyclability	(a) durability; (b) reliability; (c) reusability; (d) upgradability; (e) repairability; (f) the possibility of maintenance and refurbishment;	Requirements aspects listed in Art. 5(1)	Generic requirements on product information to final consumer on aspects listed in Art. 5(1)

236 Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives (OJ L 312 22.11.2008, p. 3).

237 Directive 2009/125/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for the setting of ecodesign requirements for energy-related products (OJ L 285, 31.10.2009, p. 10).

Legal instruments and other schemes	Short name	Aim	Art. 5(1) aspect(s) addressed	Performance requirements	Information requirements
			(g) the presence of substances of concern; (h) energy use and energy efficiency; (i) water use and water efficiency; (j) resource use and resource efficiency; (k) recycled content; (l) the possibility of remanufacturing; (m) recyclability; (n) the possibility of recovery of materials; (o) environmental impacts, including carbon and environmental footprint; (p) expected generation of waste		
Directive 2010/75/EU (Industrial Emissions Directive (IED), with activity-specific "daughter delegated acts" specifying Best available techniques	IED	The BREFs are a series of reference documents developed under the Directive 2010/75/EU on Industrial Emissions covering the industrial activities, providing descriptions of a range of industrial processes and related environmental issues, as well as their best operating conditions and emission rates	(g) the presence of substances of concern; (h) energy use and energy efficiency; (j) resource use and resource efficiency	Criteria and thresholds for certain aspects: best environmental performance levels in terms of emissions, consumption and nature of raw materials, water consumption, use of	Requirements for information provision for verification and to industries

Legal instruments and other schemes	Short name	Aim	Art. 5(1) aspect(s) addressed	Performance requirements	Information requirements
(BAT) in BAT reference documents (BREFs) [238])				energy and the generation of waste	
Directive 2011/65/EU on restriction of hazardous substances in electrical and electronic equipment[239]	RoHS	Restricts the use of certain hazardous substances in electrical and electronic equipment (EEE)	(g) the presence of substances of concern; (j) resource use and resource efficiency; (k) recycled content; (l) the possibility of remanufacturing;(m) recyclability; (n) the possibility of recovery of materials	Restrictions to the use of certain hazardous substances in EEE. These restricted substances include heavy metals, flame retardants or plasticizers. Prevents hazardous substances being leaked into the environment	It ensures a level playing field for manufacturers and importers of EEE in the European market
Directive (EU) 2022/2464 on Corporate Sustainability Reporting[240]	CSRD	Ensure informed choice for investors and stakeholders to assess investment risks arising from climate change and other sustainability issues with the disclosure of sustainability information	(o) environmental impacts, including carbon and environmental footprint;	-	Information on climate change mitigation; climate change adaptation; water and marine resources; resource use and the circular economy; pollution;

[238] Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions (integrated pollution prevention and control) (recast) https://eur-lex.europa.eu/eli/dir/2010/75/oj https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02010L0075-20110106&qid=1694710825496.

[239] Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (OJ L 174 1.7.2011, p. 88).

[240] Directive (EU) 2022/2464 of the European Parliament and of the Council of 14 December 2022 amending Regulation (EU) No 537/2014, Directive 2004/109/EC, Directive 2006/43/EC and Directive 2013/34/EU, as regards corporate sustainability reporting (OJ L 322, 16.12.2022, p. 15).

Legal instruments and other schemes	Short name	Aim	Art. 5(1) aspect(s) addressed	Performance requirements	Information requirements
					biodiversity and ecosystems.
Proposal for a Regulation amending Regulations (EU) 2018/858 and 2019/1020[241]	ELV	Facilitating the transition of the automotive sector to the circular economy, at all stages of the vehicle - from design to final treatment at end-of-life	(c) reusability; (e) repairability; (f) the possibility of maintenance and refurbishment; (g) the presence of substances of concern; (k) recycled content; (j) the possibility of remanufacturing; (m) recyclability; (n) the possibility of recovery of materials;	Requirements on recycled content targets of plastics; removability requirements for EV batteries and e-drive motors; restriction on the use of lead, cadmium, mercury and hexavalent chromium in vehicles and exemptions; circularity targets requirements on the reuse and recycling of end-of-life vehicles, on their reuse and recovery and on plastic recycling	Information requirements on removal and replacement, labelling requirements
Regulation (EU) 2024/1157 on shipment of waste [242]	SHIP	Ensure environmental protection, and reduce the risks to human health due to the shipment of waste within and beyond EU borders	(o) environmental impacts, including carbon and environmental footprint;	-	Information requirements from the Movement Document, in particular about

[241] Proposal for a Regulation of the European Parliament and of the Council of 13 July 2023 on circularity requirements for vehicle design and on management of end-of-life vehicles, amending Regulations (EU) 2018/858 and 2019/1020 and repealing Directives 2000/53/EC and 2005/64/EC (COM/2023/451 final), https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52023PC0451&qid=1742909916837.

[242] Regulation (EU) 2024/1157 of the European Parliament and of the Council of 11 April 2024 on shipments of waste, amending Regulations (EU) No 1257/2013 and (EU) 2020/1056 and repealing Regulation (EC) No 1013/2006 (OJ L, 2024/1157, 30.4.2024), https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32024R1157.

Legal instruments and other schemes	Short name	Aim	Art. 5(1) aspect(s) addressed	Performance requirements	Information requirements
					codes and classes and the chemical analysis on the composition on waste
Regulation (EU) 2025/40 of the European Parliament and of the Council of 19 December 2024 on packaging and packaging waste, amending Regulation (EU) 2019/1020 and Directive (EU) 2019/904, and repealing Directive 94/62/EC[243]	PPWR	Support Member States and businesses adequate to achieve waste reduction targets with a harmonised regulatory framework that supports investment, reduces waste and promotes high-quality recycling, which will apply equally in all EU Member States	(c) reusability; (g) the presence of substances of concern; (k) recycled content; (l) the possibility of remanufacturing; (m) recyclability; (n) the possibility of recovery of materials; (o) environmental impacts, including carbon and environmental footprint; (p) expected generation of waste	Requirements for substances in packaging, in particular a restriction on the concentration level of lead, cadmium, mercury and hexavalent chromium. Criteria for the design for recycling and requirements for 'recyclability at scale'. Requirement on minimum amount of recycled content. Requirement for reusable packaging	Information requirements for the manufacturer about label containing information on its material composition and presence of recycled content. Information requirements for suppliers of packaging to provide the manufacturer documentation to demonstrate the conformity of the packaging

[243] Regulation (EU) 2025/40 of the European Parliament and of the Council of 19 December 2024 on packaging and packaging waste, amending Regulation (EU) 2019/1020 and Directive (EU) 2019/904, and repealing Directive 94/62/EC (OJ L, 2025/40, 22.1.2025), https://eur-lex.europa.eu/eli/reg/2025/40/oj/eng.

Legal instruments and other schemes	Short name	Aim	Art. 5(1) aspect(s) addressed	Performance requirements	Information requirements
Proposal Regulation on Common Data Platform on Chemicals 2023/0453(COD), based on COM(2023)0779 [244]	CDPC[245]	As part of the one substance-one assessment Initiative (1S1A), this proposal of a regulation aims at increasing the effectiveness, efficiency and coherence of chemical assessments, thus contributing to the protection of human health and the environment. The Regulation aims to create a database on environmental sustainability-related information to complement ESPR. It also aims to ensure good cooperation between EU agencies on all aspects affecting coherence and efficiency of assessment of chemicals (such as methodology development, data exchange and solving divergences in scientific output) thus aligning work of the European Commission, the European Agency for Safety and Health at Work ('EU-OSHA'), the European Chemicals Agency ('ECHA'), the European Environment Agency ('EEA'), the European Food Safety Authority ('EFSA'), the European Medicines Agency ('EMA'), and Member State authorities.	(g) the presence of substances of concern; (o) environmental impacts, including carbon and environmental footprint		Chemicals-related data, such as: • Physico-chemical, hazard, use, exposure safety, risk, occurrence, emissions and manufacturing process-related data and information on chemical substances, on their own, or in mixtures or articles, generated or submitted under EU chemicals legislation; • Environmental sustainability related data and information, including

[244] Proposal for a Regulation of the European Parliament and of the Council of 07 December 2023 establishing a common data platform on chemicals, laying down rules to ensure that the data contained in it are findable, accessible, interoperable and reusable and establishing a monitoring and outlook framework for chemicals (COM(2023) 779 final), https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52023PC0779.

[245] Suggestion= Common Data Platform for Chemicals.

Legal instruments and other schemes	Short name	Aim	Art. 5(1) aspect(s) addressed	Performance requirements	Information requirements
					climate change related information; • Data and information on reference values.
Proposal for a Directive on Green Claims (COM (2021) 709)[246]	GCD	Ensure safety for all sectors where environmental claims or labels are unregulated at EU level, by protecting consumers and companies from greenwashing and by improving legal certainty of environmental claims	(o) environmental impacts, including carbon and environmental footprint;	-	Information requirements on environmental performances of products from claims and labels
Green Public Procurement Communication (GPP) (COM(2008) 400)[247] and EU Public Procurement Directives 2014/24/EU[248] and **Directive 2014/25/EU[249]**	GPP	GPP is a voluntary instrument within the framework of Strategic Public Procurement that provides clear, verifiable, justifiable, and ambitious environmental criteria for products and services, based on a life-cycle approach and scientific evidence base	(a) durability; (b) reliability; (c) reusability; (d) upgradability; (e) repairability;	Criteria and thresholds for aspects Art. 5	Requirements for information provision for verification and to procurers

246 Proposal for a Directive of the European Parliament and of the Council on substantiation and communication of explicit environmental claims (Green Claims Directive) (COM/2023/166 final), https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52023PC0166.

247 COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS Public procurement for a better environment (COM(2008) 400).

248 Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public procurement and repealing Directive 2004/18/EC Text with EEA relevance (OJ L 94, 28.3.2014, p. 65).

249 Directive 2014/25/EU of the European Parliament and of the Council of 26 February 2014 on procurement by entities operating in the water, energy, transport and postal services sectors and repealing Directive 2004/17/EC Text with EEA relevance (OJ L 94, 28.3.2014, p. 243).

Legal instruments and other schemes	Short name	Aim	Art. 5(1) aspect(s) addressed	Performance requirements	Information requirements
			(f) the possibility of maintenance and refurbishment; (g) the presence of substances of concern; (h) energy use and energy efficiency; (i) water use and water efficiency; (j) resource use and resource efficiency; (k) recycled content; (l) the possibility of remanufacturing; (m) recyclability; (n) the possibility of recovery of materials; (o) environmental impacts, including carbon and environmental footprint; (p) expected generation of waste		

Legal instruments and other schemes	Short name	Aim	Art. 5(1) aspect(s) addressed	Performance requirements	Information requirements
Recommendation (EU) 2021/2279[250]	EF methods	Ensure the replicability and comparability of the life cycle environmental performance of products on the market, based on the ISO 14040 and 14044 (ISO, 2006, ISO, 2020) standards	(o) environmental impacts, including carbon and environmental footprint	Calculation framework of environmental impact categories according the EF life cycle impact assessment (JRC130796[251])	-
EN 4555:2019[252]	-	The standard establishes general principles for assessing the recyclability and recoverability of energy-related products (ErP) and the ease to disassembly for end-of-life (EoL) treatment, such as recycling and other recovery operations	(k) recycled content; (l) the possibility of remanufacturing; (m) recyclability; (n) the possibility of recovery of materials; (o) environmental impacts, including carbon and environmental footprint; (p) expected generation of waste	Method for the calculation of recycling rate and recoverability rate	-
ISO 22628:2002[253]	-	The standard, stating the relevance of recoverability and recycling aspects in the design of vehicles, proposes a method for calculating recyclability and recoverability rates based on four main stages inspired by the treatment of end-of-life road vehicles	(k) recycled content; (l) the possibility of remanufacturing; (m) recyclability; (n) the possibility of recovery of	Method for the calculation of recycling rate and recoverability rate	-

250 Commission Recommendation (EU) 2021/2279 of 15 December 2021 on the use of the Environmental Footprint methods to measure and communicate the life cycle environmental performance of products and organisations (OJ L 471/1, 30.12.2021).

251 Andreasi Bassi S., Biganzoli F., Ferrara N., Amadei A., Valente A., Sala S., Ardente F., Updated characterisation and normalisation factors for the Environmental Footprint 3.1 method. Publications Office of the European Union, Luxembourg, 2023, doi:10.2760/798894, JRC130796.

252 EN 45555:2019 (E). General methods for assessing the recyclability and recoverability of energy-related products.

253 ISO 22628:2002. Road vehicles — Recyclability and recoverability — Calculation method.

Legal instruments and other schemes	Short name	Aim	Art. 5(1) aspect(s) addressed	Performance requirements	Information requirements
			materials; (o) environmental impacts, including carbon and environmental footprint; (p) expected generation of waste		
ISO 22095:2020[254]	CoC	The standard refers to a process by which inputs and outputs and associated information are transferred, monitored and controlled as they move through each step in the relevant supply chain	(g) the presence of substances of concern; (h) energy use and energy efficiency; (j) resource use and resource efficiency; (k) recycled content[255]	-	Information requirements for data collection and storage along the supply chain
ISO 14040[256]–14044[257]:2020	LCA	Life Cycle Assessment (LCA) methodology provides a quantitative framework for assessing the impacts on human health and the ecosystem quality caused by products and services with a life cycle perspective	(o) environmental impacts, including carbon and environmental footprint	General framework for Life Cycle Assessment (LCA)	-
Ökopol GmbH, sofia and RPA, 2020[258]	-	The report developed an assessment of the feasibility of different methods to support the flow of information on substances of concern (SoCs) from product supply chains to the waste operators, with the aim to support the efforts of the European Commission to improve the	(g) the presence of substances of concern	Reference to existing regulations (e.g. REACH and CLP) and related instruments	Analysis of modes of collection of information about the presence of

254 ISO 22095:2020. Chain of custody — General terminology and models.
255 These aspects could be part of the product characteristics that could be under a CoC system, but not all of them are cited in the standard (e.g. SoCs).
256 ISO 14040:2006+A1:2020. Environmental management. Life cycle assessment. Principles and framework.
257 ISO 14044:2006/Amd 2:2020. Environmental management — Life cycle assessment — Requirements and guidelines.
258 Ökopol GmbH, sofia and RPA, 2020. Information flows on substances of concern in products from supply chains to waste operators, Final report.

Legal instruments and other schemes	Short name	Aim	Art. 5(1) aspect(s) addressed	Performance requirements	Information requirements
		interface between chemicals, products and waste legislation, towards a safe and more circular economy			SoCs along the supply chain

Source: JRC's own elaboration.

Annex 3. Existing approaches to address substances in products

This annex summarises existing methodologies addressing the identification, tracking or restriction of substances in products. The methodologies presented in this annex are important in order to have an overview of how substances have been addressed in the past in different product policy contexts, e.g. the Ecodesign Directive and the EU Ecolabel, which were of inspiration in developing and applying a methodology under the ESPR.

Hazardous substances in the Methodology for the Ecodesign of Energy-related Products (MEErP, 2011)

In its current description, the MEErP already contains some references related to hazardous substances. In particular, the MEErP proposes two relevant indicators within its Task 5: Environment and Economics, and in particular in Task 5.2 Base-Case Environmental Impact Assessment, which are implemented via the **EcoReport Tool for the Life Cycle Assessment** (LCA). Such indicators address:

- Hazardous Substances banned by the RoHS Directive (2011/65/EU) but the presence of which is tolerated subject to specific exemptions: cadmium, lead, mercury, hexavalent chromium, polybrominated biphenyls (PBB) and polybrominated diphenyl ethers (PBDE);
- Substances of Very High Concern (SVHC) used in the product (as per candidate list developed under the REACH Regulation (Regulation (EC) No. 1907/2006)).

The groups of substances mentioned above are to a large extent covered by the definition of SoC provided in Article 2(27) of the ESPR, namely under its points (a) and (b) of the definition of SoC. In the case of SVHCs this is via direct reference to them under Article 2(27)(a). Organic substances listed in Annex II to RoHS, specifically PBBs, PBDEs and the four listed phthalates, all are classified in CLP Annex VI with at least one the hazard classes listed under Article 2(28)(b) or are regulated as persistent organic pollutants under Regulation (EU) 2019/1021. In the case of mercury, cadmium, lead and chromium VI compounds, their correspondence to the SoC definition will generally have to be assessed based on the specific compound present in the product.

The indicators proposed in the MEErP have to be calculated manually, and are not included within the EcoReport tool. These indicators are (section 5.3 “LCIA, impact indicators”, page 112 of the MEErP Part 1):

- Mass of Hg in product (in mg per product)[259]
- Mass of Cd in product (in mg per product)
- Mass of Pb in product (in mg per product)
- Mass of Cr(VI) in product (in mg per product)
- PBB concentration (in %, for component of homogeneous material)[260]
- PBDE concentration (in %, for component of homogeneous material)
- Total mass of SVHC on the Candidate list (in mg per product)

[259] Note that RoHS III – Annex II includes the following (% on homogeneous material): Lead (0,1 %), Mercury (0,1 %),Cadmium (0,01 %), Hexavalent chromium (0,1 %). So these were considered with different unit of measures in the MEErP, 2011.

[260] Note that RoHS III – Annex II also includes the following (% on homogeneous material): Bis(2-ethylhexyl) phthalate (DEHP) (0,1 %), Butyl benzyl phthalate (BBP) (0,1 %), Dibutyl phthalate (DBP) (0,1 %), Diisobutyl phthalate (DIBP) (0,1 %). So these were not considered in MEErP, 2011.

In addition, the following indicators corresponding to the following substances listed in Annex II to RoHS, but not mentioned in the MEErP, are relevant:

- Bis(2-ethylhexyl) phthalate (DEHP) (in %, for component of homogeneous material
- Butyl benzyl phthalate (BBP) (in %, for component of homogeneous material
- Dibutyl phthalate (DBP) (in %, for component of homogeneous material)
- Diisobutyl phthalate (DIBP) (in %, for component of homogeneous material)

As reported in section 4.1.2 "Other health-related impacts" of the MEErP Part 2 (page 111), "The reason to include the calculation of the listed SVHC by mass or concentration as indicators in the MEErP is mainly to avoid duplication of REACH/RoHS requirements. [...] A specific mass count per SVHC would be ideal, but if such information is not available (e.g. for confidentiality reasons) a total mass count is acceptable".

In addition, the European Chemicals Agency (ECHA), through its Member State Committee, and exceptionally the Commission, identify environmental/health impacts corresponding to each SVHC (carcinogenic, mutagenic, toxic for reproduction, (very) persistent, (very) bio-accumulative, etc. or show an equivalent level of concern, as per categories listed in Article 57 of REACH), but has not attributed to them quantitative characterization factors that would allow a more specific evaluation in the EcoReport Tool.

In line with the definition of the Base Case, the definition of the SVHC-content should be based, whenever possible, on a sales-weighted assessment, as the amount of SVHCs may differ between products.

Sources of information recommended by the MEErP to be used to gather concentration levels of substances in the Base Case product point towards obtaining industry-average concentrations available through e.g. industry associations, surveys to selected industries or even SDSs (Safety Data Sheets).

In the revised version of the MEErP (2024)[261] the updated indicators considered in Task 5 comprise solely those that are LCA-based, according to the Environmental Footprint (EF) method (v.3.1). Additional indicators, such as the SVHC indicator as in the MEErP (2011), need further analysis, and are not specifically investigated in the 2024 MEErP report of the JRC. In this light, the guidance provided in the present report complements the 2024 MEErP revision with regards to the analysis of chemicals.

Method to determine the use of hazardous substances in products

In 2012, Ardente and Mathieux published a method on the use of hazardous substances in products[262]. This study aimed at identifying the criticalities in the End-of-Life (EoL) of products caused by substances contained in the products, as a preparatory analysis for potential Ecodesign solutions for the minimization of risks to humans and the environment at the EoL. Their proposed method included 4 steps:

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[261] Gama Caldas, M., Eynard, U., Spiliotopoulos, C., Blengini, G., Alfieri, F., Mancini, L., Mathieux, F. and Ardente, F., *Review of the MEErP - Methodology for Ecodesign of Energy-related Products*, Publications Office of the European Union, Luxembourg, 2024, JRC136406.

[262] Ardente F, Mathieux F. (2012) Integration of resource efficiency and waste management criteria in European product policies – Second phase Report n° 3 - Refined methods and Guidance documents for the calculation of indices concerning Reusability / Recyclability / Recoverability, Recycled content, Use of Priority Resources, Use of Hazardous substances, Durability. EUR 25461 EN. Luxembourg (Luxembourg): Publications Office of the European Union. JRC73188.

— **'Step 1**. Definition of the set of substances to be considered. The set of substances to be considered has to be defined in order to set potential requirements. The set can include regulated substances (e.g. by RoHS Directive and/or REACH Regulation) and additional substances (e.g. substances identified as hazardous to human health and/or the environment as identified and listed by the CLP, the GASC (Green and Sustainable Chemistry) or the Green Screen Initiative).

— **Step 2**. Identification of components embodying the considered substances. Once the set of considered substances has been defined, it is necessary to identify if these are contained in some components of the product. This "identification" process could also require obtaining information from the manufacturers or suppliers.

— **Step 3**. Identification of treatments for the EoL of the component and of potential risks. For each component identified in the previous "Step 2", it is necessary to identify the recovery treatments that the components will undergo at EoL and potential risks related to them. This identification can be based on scientific literature or on direct feedback from the recyclers. Information about the disassembly of the components is also necessary.

— **Step 4**. Identification of key components. Key components are identified, based on results of previous steps. Key components are those components that have a content of hazardous substances that is critical for the identified EoL treatments'.

— The method provides introductory elements to support the laying of obligations of information from the manufacturer towards the actors of the waste chain and includes aspects related to the Extended Producer Responsibility (EPR).

The Chemical Task Force for the EU Ecolabel

Two Chemical Task Force (CTF) papers were developed by the JRC in 2014 and 2018, thus known as CTF1[263] and CTF2[264], in the context of the **EU Ecolabel**. Established in 1992 by Regulation (EC) 66/2010 (hereafter, the 'EU Ecolabel Regulation'), the EU Ecolabel is the EU's voluntary scheme for environmental excellence for products. The EU Ecolabel promotes products with reduced impacts during their entire life cycle, targeting the best 10%-20% products in the market. In particular, Article 6 of the EU Ecolabel Regulation highlights the importance of taking a whole life cycle perspective to the evaluation of the most significant environmental impacts, addressing especially impacts on climate change, nature and biodiversity, energy and resource consumption, generation of waste, emissions to all environmental media, pollution through physical effects and the use and release of hazardous substances. The EU Ecolabel criteria thus covers both aspects related to environmental impacts conventionally evaluated through the LCA methodology, such as contribution to global warming potential, and other "non-LCA" aspects related to health and inherent safety of products.

Article 6(6) and 6(7) of the EU Ecolabel Regulation are of particular relevance for the restriction of substances in products. **Article 6(6)** states that "*The EU Ecolabel may not be awarded to goods containing substances or preparations/mixtures meeting the criteria for classification as CMR, in accordance with Regulation 1272/2008, nor to goods containing substances referred to in Article 57 of Regulation 1907/2006*". **Article 6(7)** states that "*For specific categories of goods containing*

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[263] Dodd, N. and Cordella, M., Kougoulis, J. and Kaps, R. Findings of the EU Ecolabel Chemicals Horizontal Task Force Proposed approach to hazardous substance criteria development, Joint Research Centre, Institute for Prospective Technological Studies (Seville), 2014, https://environment.ec.europa.eu/system/files/2023-02/Chemicals%20HTF_Approach%20paper.pdf.

[264] Dodd, J., Vidal, C., Donatello, S., Kaps, R., Chemical Task Force 2, Final proposals and recommendations, Joint Research Centre (Seville), 2018, https://environment.ec.europa.eu/system/files/2023-02/ecolabel_chemical_task_force_2_final_recommendations.pdf.

substances referred to in Art. 6(6), and only in the event that it is not technically feasible to substitute them as such, or via the use of alternative materials or designs, or in the case of products which have a significantly higher overall environment performance compared with other goods of the same category, the Commission may adopt measures to grant derogations from Art. 6(6). No derogation shall be given concerning substances that meet the criteria of Article 57 of Regulation 1907/2006 and that are identified according to the procedure described in Article 59(1) of that Regulation, present in mixtures, in an article or in any homogeneous part of a complex article in concentrations higher than 0,1 % (weight by weight)".

CTF1 (2014) proposes a six-step approach for the interpretation of Art. 6(6) and 6(7) when establishing EU Ecolabel criteria, thus providing guidelines on how to handle and reduce hazards from substances and materials used in products targeted by the EU Ecolabel. The **six steps** included in the CFT1 proposal are:

- Product definition and bill of components, materials and substances
- Screening for restricted substances and hazard classification
- Product hazard substitution and green chemistry and engineering initiatives
- Screening and investigation of derogation requests
- Specification of the criteria and derogation conditions
- Specification of assessment and verification requirements

The approach is grounded on eight guiding principles:

- Feasibility for front runners
- Integrating life cycle thinking
- Preventative action based on a precautionary approach
- Reference to EU policy tools
- Proportionality within the EU criteria development process:
- Manageable administrative burden
- Verifiability
- Horizontal applicability among products

In its proposal, the CFT1 explains that the six-step approach listed above for the restriction of hazardous substances could potentially be extended to include the application of LCA to evaluate if **chemical substitution** might lead to any environmental performance trade-offs. However, this was not carried out within the CFT1 work.

Finally, in terms of **verification** of the EU Ecolabel criteria on hazardous substances, the CFT1 stresses the importance to meaningfully verify compliance with the criteria in a way that provides a high level of assurance to consumers, reflects the practical potential for applicants to obtain information from the supply chain and which excludes the potential for 'free riding' by applicants.

The Chemical Task Force 2 (2018) expands the results of the CFT1 and focuses on few specific issues related to hazardous substances such as: how to define front runners performance, when exempting substances from restrictions due to reduced exposure to potential hazards, and designing a decision tree to identify hazard classification of substances (e.g. harmonised hazard classification, joint summission, self-classification, etc.)

Moreover, the CFT2 lists and discusses the following factors which should be taken into account when derogating hazardous substances from complying with an EU Ecolabel restriction:

i. The potential presence of hazardous substances remaining in the final product,

ii. The complexity of the supply chain,

iii. The degree of control that applicants have over ingoing chemicals, and

iv. The progress made by front runners in substituting hazardous substances.

Information flows on substances of concern in products from supply chains to waste operators

This study commissioned by the European Commission and carried out by Ökopol GmbH, sofia and RPA in 2020[265], investigated information flows on substances of concern in products from supply chains to waste operators. Substances of concern were defined, for the exclusive purposes of that study, into substances that, due to their presence in the waste being treated or in the recovered material have the following effects:

- Could cause unacceptable adverse effects on human health or the environment, including but not exclusively SVHCs (named hazardous SoCs);
- Could disrupt the (foreseen) waste treatment processes and/or reduce their efficiency (named process disturbing SoCs);
- Could reduce the (technical) quality and performance characteristics of the secondary raw materials (named quality related SoCs).

Safe and circular design – A design method for dealing with substances of concern in products

In 2023, Arriola et al.[266] proposed a methodology to deal with hazardous substances in products from the **product design phase**. The method investigates the chemicals-product system and the life-cycle stages of the product, focusing on hazardous substances that pose a risk to the safety and circularity of products. These substances, referred to in this publication as substances of concern, are grouped into the following:

(i) those present in the product – intentionally added to their composition, e.g. additives, such as phthalates in flexible PVC);

(ii) those unintentionally generated by the product – by-products generated throughout the lifecycle, e.g. microplastics released from synthetic textiles; and

(iii) those used or added temporarily to the material or product for additional functions but not intended to be present in the end product, e.g. formaldehyde added to textiles during manufacturing to reduce creases, which can remain if not washed before wear.

The methodology proposed by Arriola et al. includes the following steps:

1. Analysis of the product-substance combination:
    a. Identifying substances of concern of relevance for the product according to the three types ((i), (ii) and (iii)) mentioned above;
    b. Investigating information on the substances of concern such as its concentration and function within the product, its hazards on human health and environment, and its regulatory framework

[265] Ökopol GmbH, sofia and RPA, 2020. Information flows for substances of concern in products from supply chains to waste operators, Final report.

[266] Arriola, J. B., Subramanian, V., Bakker, C., Balkenende, R. (2023) Safe and Circular Design - A design method for dealing with substances of concern in products. 5th PLATE Proceedings, 2023 Conference Espoo, Finland - 31 May - 2 June 2023, https://www.plateconference.org/call-for-contributions-2/.

2. Analysis of the context product-substance combination:
    a. Identifying emission-exposure (workers, adult/child consumers, environment) scenarios through all life-cycle stages, including the use stage and three end-of-life scenarios;
    b. Determining the most concerning emission-exposure scenarios;
    c. Analysing the relationship between the most concerning emission-exposure scenarios, the product architecture and the context;
3. Define strategies to avoid/mitigate risks from the so-called substances of concern.
4. Evaluate the selected strategies and measure their potential effects:
    a. Estimating the effects of strategies on the concerning emission-exposure scenarios;
    b. Analysing and indicating potential negative consequences of the strategy;
    c. Analysing and indicating potential trade-offs.

The current method referred to above is mainly based on a qualitative assessment and is expected to provide more robust results with the integration of Life Cycle Assessment (LCA) and Risk Assessment (RA) studies.

Annex 4. Approach to data modelling for the worst-case scenario in Section A

As explained in Section A, the definition of the chemical composition of the Base Case(s) should be represented by the **worst-case scenario**. In this sense, it is suggested to consider the highest concentration of substances in the product.

In relation to the data modelling and the calculation of substance concentrations, the representation of the **worst-case scenario** may change, depending on which product aspects (Art. 5(1) ESPR) are assessed in defining the **performance requirements** for substances.

For example, when assessing the **circularity performance** of the product (i.e. the ecodesign requirements including the product aspects (m) the possibility of recycling and (n) the possibility of the recovery of materials), the chemical composition of the BC should be taken as the highest reported.

During data collection, specific values or rather a range of values could be available. When a **range of concentrations** is available, the suggested approach in data modelling is:

1. If direct data about products are available, the maximum concentration for chemicals in a product is suggested to be used.

2. If no direct data about products are available and a mass balance approach[267] is needed (e.g. amount on product = input chemical amount – emissions), minimum values for emissions are suggested (thus greatest impact on the product but lowest effect on the environment due to direct emissions is assumed). However, case-by-case considerations might be still needed according to the product-specificity.

When assessing different product aspects related to **sustainability performance**, i.e. the ecodesign requirements addressing product aspects such as (o) "*environmental impacts, including carbon and environmental footprint",* and related product parameters, such as Annex I to the ESPR – "Product parameters", (q) "*emissions to air, water or soil released in one or more lifecycle stages of the product as expressed through quantities and nature of emissions, including noise"*, and a range of values is available, the worst-case scenario would be better represented with the highest value of the range concerning emissions data (thus minimum impact on the product but highest effect modelled on the environment).

However, with regards to the product aspect "(o) environmental impacts, including carbon and environmental footprint", it should be noted that the LCA in general and the secondary datasets for the life cycle inventory (LCI) are based on an average scenario. This implies that, when the worst case approach alone is adopted for Section A because of lack of complementary weighted averaged data, the substances along the life cycle of the Base Case and their flows may differ in the LCI compared to the results of Section A.

Substances representativeness check and uncertainty analysis

In line with the data quality requirements reported in the Commission Recommendation (EU) 2021/2279 about the Product Environmental Footprint (PEF)[268], EF compliant datasets should follow

[267] The approach based on mass balance is to be interpreted as the calculation following the principle of physical conservation of mass (input minus output) and not related to the Chain of Custody model.

[268] Commission Recommendation (EU) 2021/2279 of 15 December 2021 on the use of the Environmental Footprint methods to measure and communicate the life cycle environmental performance of products and organisations (OJ L 471/1, 30.12.2021).

four quality criteria: (i) Technological Representativeness (TeR)[269], (ii) Geographical Representativeness (GeR)[270], (iii) Time-related Representativeness (TiR)[271] and Precision (P)[272].

As reported in the Recommendation, "*the representativeness (technological, geographical and time-related) characterises the degree to which the processes and products selected depict the system analysed, while the precision indicates the way the data are derived and the related level of uncertainty*".

These criteria should be subject to a scoring procedure and contribute to the calculation of the Data Quality Rating (DQR) score, according to Formula 19 reported in the Recommendation. Five overall data quality levels (from excellent to poor) can be attained according to the DQR.

In the present methodology, the calculation of the DQR score is not suggested, except for the usual practice in the Life Cycle Inventory (LCI) for the Environmental Footprint assessment according to the PEF guidance. However, the quality criteria of the PEF are considered and adapted, providing substances-specific guidance.

High representativeness is usually achieved when the primary data can cover the whole BoM, and, in addition reflections on the following data profiles are needed:

1) **Timeframe:** chemicals present in products in the market change over time, given they could be periodically restricted under applicable regulations, thus the representativeness of data under the temporal profile should be checked.

   In particular, the proposed check should ensure that the considered chemicals were admitted in products placed on the EU market (and imported) in the time period that starts with $\mathbf{t_0}$ and ends with the **reference year ($\mathbf{t_1}$)** of the BC, defined in Task 2 'Market analysis' of the MEErP. The t_0 is calculated counting back a number of years equal to the **life-span** of the product, according to the following general formula (**Equation 2**):

Year to start to include chemicals in scope in the BC (t_0) = Reference year (t_1) – Product's lifespan (yrs)
(Equation 2)

   This approach aims to consider legacy chemicals, that could be defined as chemicals currently banned or phased-out due product restriction (mostly safety-based restriction), representing one of the major regulatory limitations when materials undergo a recycling operation, and secondary materials are placed on the market.

   Thus, the chemicals present in the product may differ from the temporal perspective adopted for the BC, depicted as a product placed on the market in the reference year.

[269] The term '"technological representativeness' used in relation to this procedure method is equivalent to "technological coverage" used in EN ISO 14044:2006.
[270] The term '"geographical representativeness" used in relation to this procedure method is equivalent to "geographical coverage" used in EN ISO 14044:2006.
[271] The term "time-related representativeness" used in relation to this procedure method is equivalent to "time-related coverage" used in EN ISO 14044:2006.
[272] The term "parameter uncertainty'' used in relation to this procedure method is equivalent to "precision" used in EN ISO 14044:2006.

Ongoing restrictions should be checked under the temporal profile of the analysed product and the selected chemicals for the BC shall be compatible with its lifespan.

A suggested check is the analysis of the date of entry into force of the restrictions of relevant chemicals (if any) under REACH, POPs Regulation, BPR, and other applicable product-specific regulations.

However, justifications for inclusion of chemicals not matching with the resulting timeframe under the profile of the applicable product restrictions could be reported on a case-by-case analysis, with e.g. evidence from test reports assessing the presence of the concerned chemical despite product restrictions were in force[273].

2) **Geography**: according to the market analysis performed in Task 2 of the MEErP, the geographical profile of the product should be known and represented in the substances identified in the base case.

3) **Technology**: according to the technology analysis performed in Task 4 of the MEErP, the current technologies employed in the manufacturing of the product should be known and considered when identifying the substances in the base case.

273 The mentioned evidence could be the result of failure in the surveillance activity.

Annex 5. Proposed questionnaire to request information on substances

Questionnaire aimed to collect information on substances and substances of concern under the ESPR.

[TEMPLATE – to be shared with stakeholders through an EU Survey when suitable]

Given that the Ecodesign of Sustainable Products (ESPR)[274] is a framework Regulation, the relevant ecodesign requirements for individual product groups are to be set in product-specific delegated acts (DAs). To this end, and before a draft product-specific delegated act is consulted on, a specific Preparatory Study is carried out for the individual product group being studied. This form aims to collect information regarding substances in products for use during the Preparatory Study work for [include name of product group, e.g. textile apparel].

The form seeks information to be subsequently used for potentially developing draft performance and/or information requirements, to then be consulted upon with stakeholders, Member States and the co-legislators via the ESPR consultation and governance process.

The form is divided into five main sections to be completed by stakeholders responding to the questionnaire.

Article 6 of the ESPR states the possibility to set out performance requirements related to product aspects identified in Article 5. Also, ESPR Article 7(5) lays down the obligation to set out information requirements on substances of concern.

Article 5(1) lists the product aspects that should be addressed by Ecodesign requirements:

(a) durability;

(b) reliability;

(c) reusability;

(d) upgradability;

(e) repairability;

(f) the possibility of maintenance and refurbishment;

(g) the presence of substances of concern;

(h) energy use and energy efficiency;

(i) water use and water efficiency;

(j) resource use and resource efficiency;

(k) recycled content;

(l) the possibility of remanufacturing;

(m) recyclability;

(n) the possibility of recovery of materials;

(o) environmental impacts, including carbon and environmental footprint;

(p) expected generation of waste.

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274 Regulation (EU) 2024/1781 of the European Parliament and of the Council of 13 June 2024 establishing a framework for the setting of ecodesign requirements for sustainable products, amending Directive (EU) 2020/1828 and Regulation (EU) 2023/1542 and repealing Directive 2009/125/EC. Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32024R1781&qid=1719580391746.

In particular, Article 6(1) states that "*Products shall comply with performance requirements related to the product aspects*". Article 6(3) states that "*Performance requirements based on the product parameter referred to in Annex I, point (f)*[275]*, shall not restrict, for reasons relating primarily to chemical safety, the presence of substances in products*."

Article 7(5) states that:

"Unless otherwise provided for under paragraph 6, point (b), the information requirements shall make it possible to track the substances of concern, throughout the life cycle of the products concerned, unless such tracking is already possible pursuant to information requirements laid down in another delegated act adopted pursuant to Article 4 covering the products concerned, and shall include at least the following:

a) the name or numerical code of the substances of concern present in the product, as follows:

    (i) name in the International Union of Pure and Applied Chemistry (IUPAC) nomenclature, or another international name when IUPAC name is not available;

    (ii) other names, including usual name, trade name, abbreviation;

    (iii) European Community (EC) number, as indicated in the European Inventory of Existing Commercial Chemical Substances (EINECS), the European List of Notified Chemical Substances (ELINCS) or the No Longer Polymer (NLP) list or the number assigned by the European Chemicals Agency (ECHA), if available and appropriate;

    (iv) the Chemical Abstract Service (CAS) name and number, if available;

b) the location of the substances of concern within the product;

c) the concentration, maximum concentration or concentration range of the substances of concern, at the level of the product, its relevant components, or spare parts;

d) relevant instructions for the safe use of the product;

e) information relevant for disassembly, preparation for reuse, reuse, recycling and the environmentally sound management of the product at end-of-life."

According to Article 2(27) of the ESPR, a 'substance of concern' means:

"a substance that:

— meets the criteria laid down in Article 57 of Regulation (EC) No 1907/2006 and is identified in accordance with Article 59(1) of that Regulation;

— is classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 in one of the following hazard classes or hazard categories:

— carcinogenicity categories 1 and 2;

— germ cell mutagenicity categories 1 and 2;

— reproductive toxicity categories 1 and 2;

— endocrine disruption for human health categories 1 and 2;

[275] use of substances, and in particular the use of substances of concern, on their own, as constituents of substances or in mixtures, during the production process of products, or leading to their presence in products, including once those products become waste, and their impacts on human health and the environment;

- endocrine disruption for the environment categories 1 and 2;
- persistent, mobile and toxic or very persistent, very mobile properties;
- persistent, bioaccumulative and toxic or very persistent, very bioaccumulative properties;
- respiratory sensitisation category 1;
- skin sensitisation category 1;
- hazardous to the aquatic environment — categories chronic 1 to 4;
- hazardous to the ozone layer;
- specific target organ toxicity — repeated exposure categories 1 and 2;
- specific target organ toxicity — single exposure categories 1 and 2;
- is regulated under Regulation (EU) 2019/1021; or
- negatively affects the reuse and recycling of materials in the product in which it is present"

The ESPR also envisages the possibility to establish exemptions for substances of concern defined under Art. 2(27) (b), (c), and (d) from the tracking obligation.

Article 7(6) states that:

"where the Commission sets out information requirements in a delegated act adopted pursuant to Article 4, it shall, where relevant: […] (b) provide duly justified exemptions for substances of concern or information elements from such information requirements referred to in the first subparagraph of paragraph 5, based on the technical feasibility or relevance of tracking substances of concern, the existence of analytical methods to detect and quantify them, the need to protect confidential business information or in other duly justified cases; substances of concern within the meaning of Article 2(27), point (a), shall not be exempted if they are present in products, their relevant components or spare parts in a concentration above 0,1 % weight by weight"

In order to seek information to be used for the potential development of performance and/or information requirements, this form is divided into 5 main sections to be completed by stakeholders providing information for the work carried out under the Preparatory Study of the product group [include name of product group, e.g. apparel textiles].

- Section 1 aims to collect information about substances in the relevant product group, with the purpose of contributing to building the life cycle inventory and in particular, a "bill of chemicals";
- Section 2 intends to obtain information on specific substances known or suspected of having an impact on any of the 16 product aspects listed in Article 5(1);
- Section 3 aims to collect information about each substance of concern that could "negatively affect the reuse and recycling of materials in the product in which it is present;" i.e. those substances of concern that fall under the definition (27) point (d) of Article 2 of the ESPR;
- Section 4 asks for stakeholder views on the setting a threshold or thresholds, in terms of substance concentration, below which information requirements would not apply. It also seeks views on the possible timeline for the application of information requirements for substances of concern, and whether a differentiation between substances of concern would be necessary; and

— Section 5 tries to collect information on possible exemptions on the tracking of substances of concern that could be considered for their potential inclusion in a future Delegated Act for [name of the product group under analysis].

The following questionnaire is provided to collect relevant information in these respects.

Note: Tables selected in **blue** are to be completed in by stakeholders.

General information

Contribution publication privacy and confidentiality

Contact name	
Organisation	
Email	
Telephone No.	
Supplementary documents attached	

I consent to the publication of any information in my contribution in whole or in part (which may include quotes or opinions I express) provided that it is done anonymously. **I declare that nothing within my response is unlawful or would infringe the rights of any third party in a manner that would prevent publication.**	☐Yes

Please do not include any personal data in the contribution itself if you want to remain anonymous.

If you wish to share additional information in the form of data files (e.g. see section 1), position papers, etc, please submit via e-mail to [e-mail address] indicating, as applicable, any limitations to the use / publication of the information provided.

Section 1. Chemical information towards Life Cycle Inventory

In this section, stakeholders are requested to provide information to enable building the life cycle inventory of the product group and product category regarding components, materials, etc. Information is also requested on intentionally and non-intentionally added substances (e.g. impurities from the production of raw materials or from recycled content (where present), remnant substances from process auxiliaries, etc.) in the product and from its entire life cycle. In particular, chemicals and materials remaining in the product group/ category are relevant, and also those used or present throughout the product's life-cycle (e.g. associated emissions), including in the waste phase.

Stakeholders are kindly requested to provide in a suitable file format (e.g. an Excel spreadsheet) detailed information on process chemicals, auxiliary chemicals and non-intentionally added substances, including impurities (to the extent that this is known) relevant to the product group / category. To the extent possible, the name and chemical identifiers of each substance should be provided (e.g. EC / CAS numbers) as well as its function, life-cycle stage for which it is relevant, and the average and maximum concentrations at which substances are used and, as applicable, remain in the product. Such information should be submitted in a separate file or files.

Section 2. Information on substances connected to specific product aspects

Furthermore, information is sought on substances that are known or suspected of affecting the following product aspects, as listed in Article 5(1) of the ESPR. The information can also relate to a possible relationship between a substance, or a family or a type of substances, and the relevant product aspect.

Product aspect:	**Explanation about how the substance affects the product aspect, including information/ relationship/ possible impacts, etc.**	**Substance identification (name, CAS Number, etc.)**
(a) durability;		
(b) reliability;		
(c) reusability; See also section 3		
(d) upgradability;		
(e) repairability;		
(f) the possibility of maintenance and refurbishment;		
(h) energy use and energy efficiency;		
(i) water use and water efficiency;		
(j) resource use and resource efficiency;		
(k) recycled content;		
(l) the possibility of remanufacturing;		
(m) recyclability; See also section 3		
(n) the possibility of recovery of materials;		
(o) environmental impacts, including carbon and		

environmental footprint;		
(p) expected generation of waste		

Section 3. Substances of Concern that negatively affect reuse and recycling

In this section, stakeholders are requested to provide information about Substances of Concern as per ESPR Article 2(27), point (d), subsequently referred to as "SoCs (d)", defined as a substance that "*negatively affects the reuse and recycling of materials in the product in which it is present*". In this regard, links to responses to points c) and k) to n), above should also be noted.

"Substances of Concern (d)" can be related to:

— Existing regulatory limitations[276] to the placing on the market or use of substances;

— Customer-driven limitations[277] along the supply chain;

— Technical constraints, interfering with the processes leading to reuse; preparing for reuse or recycling; or with the functionality, usefulness, value and aesthetics of the resulting recycled materials or products for reuse (as specified in Article 5(14)). These can be "process-disturbing SoCs"[278] or "quality-disturbing SoCs"[279],

Explanation regarding how the SoC *"negatively affects the* ***RECYCLING*** *of materials in the product in which it is present".*	**Substance identification** (name, CAS, etc.)	**Type of limitation** (specify if regulatory, customer-driven, process disturbing, quality disturbing, other)

276 Potential limitations to reuse or recycling may arise from product and waste legislation, as recycled or reused products may not be able to comply with existing requirements applicable to products placed on the market.

277 Specific requirements from industry practice may address the presence of certain substances in products, which may not be met by reused and recycled materials. These limitations or pressures are exerted by actors of the supply chain, sometimes on behalf of the final consumer, on the waste chain actors and on the suppliers of the raw materials, and can occur even in compliance with derogations from regulatory obligations.

278 "Process-disturbing SoCs", are substances that can disrupt the waste treatment process making the reuse, or recycling process more complicated, costly, environmentally impactful, or energy- or resource-demanding.

279 "Quality-disturbing SoCs" are substances that reduce the (technical) quality and performance characteristics of the recyclate. These include substances that bring alterations in the mechanical, technical, chemical and physical properties of the recyclate, preventing it from achieving the desired/expected performance and therefore being taken up by the market or being able to compete with virgin alternatives.

Explanation regarding how the SoC *"negatively affects the* ***REUSE*** *of materials in the product in which it is present".*	**Substance identification** (name, CAS, etc.)	**Type of limitation** (specify if regulatory, customer-driven, process disturbing, quality disturbing, other)

Section 4. Thresholds and timeline for information requirements on SoCs

Article 7(5) of the ESPR specifies that "*the Commission may, where appropriate for the product group concerned, set thresholds for when the information requirement regarding substances of concern is to apply*".

Similarly, Article 7(6) states that when setting out information requirements in a delegated act it shall, where relevant, "*lay down dates of application of such information requirements referred to in the first subparagraph of paragraph 5, differentiating between substances of concern where necessary*".

Do you consider that generic or specific thresholds should be set for *[name of the product group under analysis]* **below which information requirements on substances of concern should not apply? In your opinion, what generic and / or specific thresholds should be set below which information requirements on substances of concern should not apply. Please justify your proposal.**

The obligation to provide information on substances of concern in products within the scope of an ESPR delegated act applies by default to all substances of concern, without prejudice to thresholds and/or specific exemptions that may be defined. **Should differentiated dates be set on the application of this obligation, for instance for different types or categories of substances of concern, relevant to** [name of the product group under analysis]**? Please justify your proposal.**

Section 5. Exemptions from ESPR information requirements.

Stakeholders are requested to provide details on the substances of concern that are used or present over the life cycle of [*name of the product group under analysis*] and that may qualify as possible exemptions from required information requirements.

Information is requested regarding potential exemptions for substances of concern under the ESPR Article 2(27) (b), (c) and (d).

The information collected from stakeholders *via* this questionnaire will be used as a starting point for addressing the relevance of setting exemptions, if any, to information requirements on substances of concern under Art. 2(27) (b), (c) or (d). Providing this feedback should by no means be interpreted as a guarantee of an exemption being taken up in the recommendations of the Preparatory Study, or in the subsequent product-specific delegated act. Stakeholders are invited to provide as much information as possible to justify the reasons that they see might justify deviating from the default legal obligation to provide information on the presence of SoCs in products.

According to **Art. 7(6)(b)** of the ESPR:

"where the Commission sets out information requirements in a delegated act adopted pursuant to Article 4, it shall, where relevant: [...] (b) provide duly justified exemptions for substances of concern or information elements from such information requirements referred to in the first subparagraph of paragraph 5, based on the technical feasibility or relevance of tracking substances of concern, the existence of analytical methods to detect and quantify them, the need to protect confidential business information or in other duly justified cases; substances of concern within the meaning of Article 2(27), point (a), shall not be exempted if they are present in products, their relevant components or spare parts in a concentration above 0,1 % weight by weight";

Repeat the tables below as many times necessary as required to address the specific substances for which an exemption is proposed. Different fields should be completed to the extent relevant and possible.

Substance information

Chemical substance name(s) (IUPAC[280] nomenclature, or another international name when IUPAC name is not available)	
Other name(s), including usual name, trade name, abbreviation	

[280] International Union of Pure and Applied Chemistry.

EC (European Community) number[281]	
Chemical Abstract Service (CAS) name(s) and number(s) (if available)	
Current EU regulatory status State the most relevant EU or international legislation regarding the substance, in particular as relevant to the product group concerned, and its consequences.	
Type of substance of concern according to Article 2(27) of the ESPR (i.e. (b), (c) or (d)). Please specify if the substance falls under more than one type.	
If a substance of concern under Article 2(27) (b), state the harmonised classification(s) for the substance	
References to key technical / economic reports and studies relative to the substance's properties, impacts, uses and alternatives, e.g. risk assessments, analysis of alternatives, socio-economic assessments, etc. (EU or global level).	
Function of the substance in the product lifecycle (if impurity, please state [*impurity*])	
Is the substance present in the product or in its component(s)?	
If yes, state the location of the substance	

281 As indicated in the European Inventory of Existing Commercial Chemical Substances (EINECS), the European List of Notified Chemical Substances (ELINCS) or the No Longer Polymer (NLP) list or the number assigned by the European Chemicals Agency (ECHA), if available and appropriate.

If not, state the life cycle stage in which the substance is used or present	
If the substance is present in the product or in its component(s), state the typical concentration in the final product and specific components (concentration ranges are accepted)	

Additional information with regard to possible exemptions

Technical feasibility	
Is it possible to track the substance?	
If no, state the reasons *(please explain thoroughly)*	
Relevance of tracking	
Is it relevant to track the substance?	
If yes, is it possible to provide information on all or some of the elements that must be disclosed by information requirements on substances of concern? (*you can find the list of elements in Art. 7(5) of the ESPR – also reported at the beginning of this questionnaire*)	
If no, justify lack of relevance and indicate any obstacles to tracking the substance? *(please explain thoroughly)*	
Other reasons *(please explain thoroughly)*	
Existence of analytical methods or data to detect and/or quantify substances of concern	
Are analytical methods to detect and quantify the substance of concern currently available at sufficient commercial scale/capacity globally? *(please explain thoroughly)*	

If not, are there any obstacles to develop them or to their widespread availability? (please explain thoroughly)	
Can information about the presence of the substance of concern, that would enable meeting the information requirement, be found in Safety Data Sheets available for the mixture or its constituent substances? (please explain thoroughly)	
Is it possible to calculate/estimate the final concentration of the substance in the product, its components or spare parts, based on information from actors in the supply chain? *(please explain thoroughly)*	
Protection of confidential business information (CBI)	
If there is a need to protect CBI, is it related to intellectual property, business-related information, or other? *(please explain thoroughly)*	
What information out of the elements that must be disclosed by information requirements on substances of concern should be omitted in the interest of protecting CBI and why? (you can find the list of elements in Art. 7(5) of the ESPR – also reported at the beginning of this questionnaire) *(please include justification and explain thoroughly)*	
Other duly justified reasons	
Please explain	

Additional question:

Do you have any additional comments or observations relative to substances, particularly substances of concern, in [*name of the product group under analysis*] **in the context of the implementation of the ESPR?**

Annex 6. Case study

The aim of this annex is to show how to apply the method developed for Task B5 of ESPR in practice, as well as to share lessons learnt and provide suggestions, where applicable, to the developers of Preparatory Studies.

The Case Study has been organised in sections, following the structure of the method reported in Sections A-C. At the end of each subsection text boxes are provided explaining the main difficulties and lessons learnt from the testing. An iterative process was followed together with the drafting of the method, based on a learning-by-doing approach.

The testing was made on a simplified Case Study from the textile sector, taking advantage of the Preparatory Study under development for textile products.

This Case Study is acknowledged to be of a simplified nature compared to a full assessment on substances required in a Preparatory Study, since no extensive stakeholder consultation (in the sense of the methodology developed under Task B5) was made in this context. However, limited feedback from specific stakeholders (not publicly available) was collected via *ad hoc* consultation. In particular, one textile retailer provided quantitative data about substances used in textile processes and another stakeholder gave information regarding substances-related issues at the end-of-life stage.

Thus, as clarified in each subsection, this Case Study shows the actions that developers of a Preparatory Study (hereafter 'Preparatory Study team') could undertake when primary data concerning chemicals are not available, and when the only available option is to rely on literature analysis. In addition, of course, the process can and should be complemented with feedback from stakeholders. The challenges and limitations of this Case Study are reported in boxes at the end of each section. The suggestions reported reflect the way challenges have been tackled, thus the proposed approaches do not have the ambition to represent a one-fit-for-all solution, given the specificities of the product group under assessment. However, the suggestions may inspire general reflections for many product groups.

Disclaimer: the scope of the current Case Study is to test the Task B5 Method. The outcomes of the assessment reported below, which are also based on assumptions, should neither be considered exhaustive, nor representative of the product group under investigation.

The Case Study **does not follow the simplified approach** described in the proposed method, but rather the "full" approach is applied, with the purpose of illustrating all the steps that may be potentially undertaken. However, the approach followed in the Case Study is not binding for the development of any Preparatory Study, including that for textiles.

6.1 Testing of Section A: Preliminary steps for the method

The product group considered in the Case Study is "apparel textiles".

The list of major data sources considered, the inventory of substances and those considered and quantified in the Base Case are reported in the subsections below.

Data sources

A compendium of all data sources considered for the Case Study is reported below:

— **Best available techniques (BAT) reference document (BREF) for the textiles industry**[282] (Roth et al., 2023), hereafter referred to as the "BREF for textiles". It includes

[282] Joze Roth, Benoit Zerger, Damien De Geeter, Jorge Gómez Benavides, Serge Roudier, Best Available Techniques (BAT) Reference Document for the Textiles Industry, Publications Office of the European Union, Luxembourg, 2023, doi:10.2760/355887, JRC 131874.

the list of Restrictions that apply specifically to the textile sector from Annex XVII in REACH, information about SVHC under REACH and additional information about substances relevant for the textile sector specifically addressed by other chemical regulations, such as the Biocidal Products Regulation (BPR) and the Regulation on Persistent Organic Pollutants (POPs).

- **Reference Document on Best Available Techniques in the Production of Polymers** (EC, 2007)[283].
- **Draft Preparatory Study on textile products** (1st Milestone, ESPR) (JRC, 2024)[284].
- **Draft Product Environmental Footprint Category Rules (PEFCR), Apparel and Footwear** (Technical Secretariat, 2021)[285].
- **Draft Product Environmental Footprint - Representative Product (PEF-RP) study report, Apparel and Footwear**, Annex I (PEFCR Technical Secretariat, 2023) (a draft version of PEFCR Apparel and Footwear was used at the time of drafting this report, however it should be noted that the final version of the PEFCR has been recently published[286]).
- **Literature and textile companies test** reports.

The Base Case

The Base Case was chosen considering one of the ten product categories identified in the Preparatory Study on textile products (1st Milestone):

- 01: T-shirts;
- 02: Shirts and blouses;
- 03: Sweaters and midlayers;
- 04: Jackets and coats;
- 05: Pants and shorts;
- 06: Dresses, skirts and jumpsuits;
- 07: Leggings, stockings, tights and socks;
- 08: Underwear;
- 09: Swimwear;
- 10: Apparel accessories

The Base Case chosen for the Case Study is **03 "Sweaters and midlayers"**, since, according to the bill of materials, it presents the highest complexity in terms of number of materials. A broader representation of substances associated to the materials aimed to ensure the identification of the main issues related to the use of substances.

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283 https://eippcb.jrc.ec.europa.eu/sites/default/files/2019-11/pol_BREF for textiles_0807.pdf.

284 Delre, A., Perez Arribas, Z., Senatore, V., Garcia John, E., Kouloumpis, V., Napolano, L., Moldovan, S., Molina, C., Mollá, K., Gallego, E., Balaguer, A., Wolf, O., Preparatory study on textiles for product policy instruments, 1st Milestone, 2024, https://susproc.jrc.ec.europa.eu/product-bureau/product-groups/467/documents.

285 Technical Secretariat, DRAFT PRODUCT ENVIRONMENTAL FOOTPRINT CATEGORY RULES (PEFCR), APPAREL AND FOOTWEAR, Version 1.2, 7 July 2021.

286 Technical Secretariat, 2025, PEF Apparel & Footwear v. 3.1– The Product Environmental Footprint https://pefapparelandfootwear.eu/.

While "Jackets and coats" (product category 04) is expected to be of a similar or higher complexity than "Sweaters and midlayers", product categories 04 and 05 were not selected in the Case Study, since natural leather is characterized by a very complicated supply chain and treatment steps.

Some information for detailing the Base Case from available data sources is reported in **Table 24**.

Table 24. Details of the Base Case.

Sub-category (Base Case)	Sweaters and midlayers (knitted type)
Function	Garment to keep the upper body warm and covered
CPA code	14.39.10 Jerseys, pullovers, cardigans, waistcoats and similar articles, knitted or crocheted (en)
CN code[287]	6110 Jerseys, pullovers, cardigans, waistcoats and similar articles, knitted or crocheted
Reference year[288] **and average lifespan**[289]	2019[290] and 85 wears (corresponding to 6.6 years)[291], 5 wears prior to washing (corresponding to 17 lifetime washings)
Weight	0.5 kg

Source: JRC's own elaboration based on and adapted from the data sources.

Bill of Materials (components and materials of a product)

The aim of the testing in this section is to provide a description of the Base Case, focusing on the components and materials of the Base Case. In particular, the final objective is to map the Base Case with the information about components and the "bill of materials".

The identification of the composition for the Base Case is based on the available data sources from the relevant ones listed for the Case Study and where the weighted average of the market shares for each relevant product according to market reports and/or market data specialists are considered. In **Table 25**, approximate weight fraction of the materials are reported.

The starting information for the definition of the bill of materials was the input amount of each material. The values for the bill of materials were, then, calculated in this Case Study assuming proportionality between the input and final material weight. Based on expert judgment from literature analysis, the representative weight for the Base Case is 0.5 kg.

For this Base Case, according to available information, components[292], as defined in Art. 2(2) ESPR, were not identified (see **Box 5**).

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287 Commission Implementing Regulation (EU) 2023/2364 of 15 October 2023 amending Annex I to Council Regulation (EEC) No 2658/87 on the tariff and statistical nomenclature and on the Common Customs Tariff, https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:L_202302364

288 The reference year represent the reference year to gather the information required in Tasks 1-4 in the MEErP.

289 The assessment of the CPA (classification of products by activity) codes, of the lifespan of the BC and of the weight are not specific requirements for the methodology, as they are part of the Preparatory study. They are reported at this stage to provide a complete picture of the Base Case. Moreover the lifespan is necessary for subsequent assessment required under Task B5 methodology.

290 At the moment of the drafting the Case Study, the reference year considered in the Draft Preparatory study was 2019.

291 Laitala, K.; Klepp, I.G.; Henry, B. Does Use Matter? Comparison of Environmental Impacts of Clothing Based on Fiber Type. Sustainability 2018, 10, 2524. https://doi.org/10.3390/su10072524

292 'component' means a product intended to be incorporated into another product.

The column 'Details' provides information on materials with recycled content, materials in direct contact with the consumer and materials with potential releases to the environment during use phase.

Table 25. Bill of materials[293] for the Base Case in this Case Study.

Materials (m_i)	Approx. weight fraction [%]	Details
Cotton	41.5%	Potentially in direct dermal contact with consumer Potential release of dyes/ finishing /microfibres during use (domestic washing)
Wool, sheep	30%	Potentially in direct dermal contact with consumer Potential release of dyes/ finishing /microfibres during use (domestic washing)
Polyester	15%	Potentially in direct dermal contact with consumer Potential release of dyes/ finishing /microfibres during use (domestic washing)
Cashmere [294]	5%	Potentially in direct dermal contact with consumer Potential release of dyes/ finishing /microfibres during use (domestic washing)
Acrylic fibre	3.5%	Potentially in direct dermal contact with consumer. Potential release of dyes/ finishing /microfibres during use (domestic washing)
Polyethylene terephthalate (PET), recycled	3%	Potentially in direct dermal contact with consumer Potential release of dyes/ finishing /microfibres during use (domestic washing) It is a recyclate material.
Viscose fibre	2%	Potentially in direct dermal contact with consumer Potential release of dyes/ finishing /microfibres during use (domestic washing)
Nylon 6.6	1.4%	Potentially in direct dermal contact with consumer Potential release of dyes/ finishing /microfibres during use (domestic washing)

Source: JRC's own elaboration based on the data sources.

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293 For simplicity, apparel trims (i.e. button, label, zip) are not encompassed in this assessment.
294 Cashmere corresponds to Wool, goat (cashmere).

Box 5. Comments and lessons learnt from the testing on Section A: Preliminary steps for the method (focus on the bill of materials).

The Case Study presents two deficiencies, caused by lack of data:

In general, any material or substance (e.g. sewing threads, adhesives, etc.) used as a means of joining elements should be mentioned in the bill of materials, particularly if they are made of different materials compared to the ones listed in **Table 25**. In this Case Study, no information about these materials was available;

Since components (as defined in Art. 2 (2) of ESPR) are missing, material types are listed separately and reported in **Table 25**, according to available data source. Thus, it is not possible to understand whether they are blended all together or partially blended and according to which designs. A suggestion, therefore, could be to define, with the aid of stakeholders' inputs, additional information on how materials are worked and bound together. These details can be reported through an additional level in the Base Case bill of materials, named as e.g. "materials group" (an example is reported immediately below), which may result relevant for the location of substances. According to available data sources, in the present Case Study materials are always listed separately.

Materials group	Materials	Weight fraction [%]	Details
Blend 1 (wrists and roundneck)	Cotton, polyester		
Blend 2 (arms and bust)	Cotton, wool, cashmere		

Substances in the product and along the life cycle stages

The aim of the testing in this section is to identify the chemical composition of the Base Case with the information on intentionally added substances.

In this Case Study, the mapping of the chemical composition of the Base Case, i.e. knitted product from the category sweaters and midlayers, was made according to literature findings, mainly relying on the BREF for textiles, taking into account the materials identified in **Table 25**. The BREF for textiles depicts the complexity of a global supply chain, reporting also information about substances limited in the EU, but that may be used in other non-EU countries, e.g. pesticides, as well as including information from international standards for textile products, such as OEKO-TEX. The BREF for textiles does not cover the production of man-made fibres (e.g. viscose, polyester, nylon, acrylic), which are instead addressed in the BREF on polymers. Therefore, in the Case Study, only the substances used in the manufacturing of viscose fibres were considered (based on data from BREF on polymers) as an example, unless specific information about substances in other man-made fibres was available in the BREF for textiles.

The selection of the relevant manufacturing processes, and the related chemicals, from the BREF for textiles was made according to the available data sources. Given the draft status of some of the available data sources, additional manufacturing processes were considered in the Case Study, as they provide a more comprehensive overview of the product under assessment. These manufacturing processes (e.g. different dyeing techniques depending on the type of fibre) were identified based on the BREF for textiles and considered suitable for the product under assessment.

Building of the inventory of substances

The identification of the **functional substances** for the inventory was conducted considering a 'worst-case' scenario, given that it was impossible to use a weighted average approach due to a lack of data on the relevant distribution of substances in the relevant products. This approach has the added value of capturing a broader array of legacy substances or substances which may be a source of concern.

A simplified assessment for complex products[295] (see Section A) was followed for assessing substances. As such, for each function required, and in each manufacturing process, alternative possible substances were considered to those flagged in the BREF for textiles as being the most hazardous (i.e. toxic for human health and for environmental receptors) or problematic from an environmental point of view (e.g. eutrophication potential). A full description of processing steps, functions and substances considered is reported in **Table 63** of **Appendix I**, together with the rationale behind the choice of the substances, as reported in the BREF for textiles and in complementary sources. As an example, the substance 'white mineral oil' (CAS 8042-47-5) was selected for lubricant function in spinning fibres because of "Disadvantages of high add-on, low temperature stability (they smoke during high-temperature treatments), poor biodegradability, presence of polyaromatic hydrocarbons and generation of difficult-to-sediment sludge in biological wastewater treatment plants" (BREF for textiles).It is important to highlight that the BREF for textiles provides in-depth information about the manufacturing stage (i.e. the production of the main product), while the raw material acquisition (for fibre production) and pre-processing are considered to a lesser extent. Thus, when assessing the environmental footprint for the definition of performance requirements, LCA disaggregated datasets for raw materials production for fibres represent a suitable tool to complement the information gathered in the predominantly industrial process-related BREF and to assess the influence of substances. However, for the definition of the inventory of substances and of the information requirements in first instance the data from BREF can be considered to be a sufficiently good starting point.

[295] See **Annex I** of the main text for the definition.

The functions needed in each manufacturing processes were identified according to the formulations/recipes in the BREF for textiles which provides the composition of substances ingredients used in the different treatments, considering conventional and non-optimised technologies.

The BREF for textiles seldom reports the CAS number of the substances; also sometimes substance families are mentioned, rather than specific substances. Thus, the CAS numbers were searched for in the ECHA CHEM public chemicals database[296] and other websites dealing specifically with chemicals (e.g. PubChem[297]). Where substance families (e.g. fatty amine ethoxylated) are mentioned in the BREF for textiles, more than one substance was reported for each family according to literature findings.

Where when only limited information regarding specific categories of chemicals was available (e.g. dyes), additional sources of data were considered, such as the AFIRM Restricted Substance List (RSL)[298], consistent with the worst-case scenario.

The same procedure was followed also for the identification of the **process substances**, e.g. auxiliaries using the relevant data sources available.

In the method, it is proposed to also report the **maximum concentration** for each substance. For simplicity in the Case Study the maximum value was considered in the following steps, for the selection and quantification of substances for the Base Case.

Intentionally added substances

The selection of **functional substances** for the Base Case should be conducted considering the most representative substances from the inventory. In this Case Study, limited information was available to assess which substances were the most representative. Thus, as a general principle, those substances which have been restricted for a long time (at least in the EU) were not considered for the Base Case, unless evidence showed that these substances could still be considered relevant.

The quantification of the substances in the definition of the Base Case, i.e. taking into account the actual shares of materials in the Base Case, was conducted mainly considering the information from the BREF for textiles and other literature; however, when such information was missing, information provided by a textiles retailer via bilateral exchanges complemented the assessment. The referred information describes the amount of substances needed for each function, but was almost never substance-specific. Thus, these data were not used to confirm the use of specific substances considered in this Case Study, but rather they were used as an indication of the amount of generic substance needed for a certain function.

When a range of concentrations was available, the chemical concentration in the materials and in the Base Case was taken as the highest reported. This approach was applied in two different situations, when (i) data directly referred to the product were available or (ii) when the mass balance between the amount of input process chemical and emissions was used.

The identification of the functions of substances and the related concentrations is reported by reference to both materials and products (**Table 26**). Given the high number of substances and the simplified nature of this Case Study, only one representative substance for each function is

296 https://echa.europa.eu/fr/substance-information/.

297 https://pubchem.ncbi.nlm.nih.gov/.

298 The Restricted Substances List created by AFIRM aims guiding supply chain participants seeking to increase product quality and safety or reduce their environmental impact by limiting the use of certain substances in apparel and footwear. The list includes substances currently subject to legislated limits around the world, as well as limits based on best practices in the apparel and footwear industries (description from https://afirm-group.com/afirm-rsl/).

reported hereafter. However, as mentioned above, the full list of substances identified as relevant for this assessment can be found in **Table 63** of **Appendix I**.

The same procedure was followed also for the identification of the **process substances**, e.g. auxiliaries.

The concentration reported for each substance in the Base Case (c_{BC}) in **Table 26** represents the amount needed to fulfil the function.

In addition, since this Case Study did not rely on stakeholder consultation, assumptions were made about the sequence of the manufacturing processes. These assumptions may not provide the full technological representativeness.

The main assumptions are:

- The final weight of the Base Case is assumed to include the weight of substances considered in it.
- In the production process, no data about number of reuses of baths for wet processes[299] were available, thus the substances were allocated entirely to the Base Case, with the exception of the dyeing process where one cycle of use is considered for the spent bath according to available information provided by a textiles retailer.
- No distinct technologies are considered for spinning and knitting, thus the substances are assumed not to change.
- A washing process was considered to wash the fabric from the auxiliaries used for spinning and knitting, before bleaching of the fabric. A heat setting process was added solely in terms of resulting emissions (i.e. VOCs from mineral oil).
- The dyeing process was differentiated in the Case Study according to the type of fibre (use of direct, disperse and reactive dyes), in order to investigate differences in the type of substances, consumption values and emissions.
- It is assumed that before dyeing the input materials are all sized to the final weight; thus, depending on the process of the value chain and its position in the manufacturing flow, the amount of chemical on the product resulting from that process was calculated with reference to:
    - the weight of the input material, if the process occurs at the beginning of the manufacturing stage, where no material losses are supposed to occur (e.g. spinning, knitting, scouring.). In this case an allocation based on the proportionality to the final material weight was needed.
    - the weight of the final material, if the process occurs at the end of the manufacturing stage where the product has the final size (e.g. dyeing, finishing). No allocation was applied in this case.
- it is assumed that the finishing process for water repellence and biocidal treatments, assumed as the last process of the manufacturing stage (see **Figure 13**), is applied to the final product, thus substances involved in finishing are considered as being uniformly distributed onto all materials.

[299] According to the BREF for textiles 'Wet processes essentially consist of dyeing and other ancillary operations carried out either in loose fibre or yarn form.'

Table 26. Chemical composition of the materials and concentrations of representative functional substances defined in the Base Case (c_{BC}). The approach of highest concentration in product was followed[300] in data modelling for the worst-case scenario, that considers low value for emissions and high value for chemicals in product, in case a range of data was available.

Materials (m_i)	Function description	Functional chemicals (CAS number)	Mass (g)	Conc. In material $c_{BC,material}$ (% w/w)	Conc. in product $c_{BC,product}$ (% w/w)	Details (location)	Set-up for calculation (i.e. mass balance[301]/direct data on product) and sources
Acrylic fibres	Synthetic polymer	Acrylic (9065-11-6)	15.49	89.38%	3.10%		Mass balance, net amount (without substances, both intentionally and non intentionally added) from the materials shares data
	Dyes	Disperse Blue 35 (12222-75-2)	9.44E-01	5.45%	0.19%	surface	Mass balance, considering mass of input generic standard disperse dye[302] (Table 4.81 BREF for textiles), number of uses of bath equal to 1 for batch dyeing (information provided by a textiles retailer) and the percentage of non-fixed dye discharged (Table 2.16 BREF for textiles, Euratex data) (generally referred to disperse dyes)
	Water-repellent agents	Polytetrafluoroethylene (PTFE) (9002-84-0)	2.86E-01	1.65%	0.06%	surface	Direct data on fibres for the function 'water repellent' (Information provided by a textiles retailer) (generally referred to e.g. polymers and fluorocarbons), assumed referred to a dispersion of PTFE. The amount of components of the mixture were calculated considering complementary information from safety datasheets of a mixture with PTFE for coating[303] [304] (proxy)
		2,6,8-Trimethyl-4-Nonyloxypolyethyleneoxyethanol (60828-78-6)	1.56E-02	0.09%	<0.01%	surface	

300 See **Annex IV** of the main text for more rationale on approaches on data modelling.

301 The approach based on mass balance is to be interpreted as the calculation following the principle of physical conservation of mass (input minus output) and not related to the Chain of Custody model.

302 The standard recipe was chosen because it requires the highest number of auxiliaries, in line with the worst-case approach.

303 https://www.quintech.de/wp-content/uploads/2020/07/SDS-TeflonDISP30-2018-ENG.pdf. The source is consulted only for the purpose of obtaining information about the composition of the mixture. It is not intended as a proof of compliance with Annex II of REACH.

304 https://www.inolub.com/pdf/Inolub%20WD%20SDS_Eng.pdf. The source is consulted only for the purpose of obtaining information about the composition of the mixture. It is not intended as a proof of compliance with Annex II of REACH.

Materials (m_i)	Function description	Functional chemicals (CAS number)	Mass (g)	Conc. In material $c_{BC,material}$ (% w/w)	Conc. in product $c_{BC,product}$ (% w/w)	Details (location)	Set-up for calculation (i.e. mass balance[301]/direct data on product) and sources
	Biocides	(benzothiazol-2-ylthio)methyl thiocyanate; TCMTB (21564-17-0)	8.84E-04	0.01%	<0.01%	surface	Direct data on product for PES cloth (assumed for all BASE CASE) (Avagyan et al., 2015)[305]. The mentioned source is about benzothiazole derivative. For the Case Study, a derivative approved for use as active substance under BPR[306] is considered.
Cashmere	Natural animal hair	Keratine (68238-35-7)	19.59	80.27%	3.92%		Mass balance, net amount (without substances, both intentionally and non intentionally added) from the materials shares data
	Dyes	Reactive Blue 72 (61968-93-2)	1.89	7.76%	0.38%	surface	Mass balance, considering mass of input dye (BREF for textiles Table 4.71), number of uses of bath equal to 1 for batch dyeing (Information provided by a textiles retailer) and the percentage of non-fixed dye discharged (Table 2.16 BREF for textiles, Euratex data) (generally referred to reactive dyes)
	Water-repellent agents	Polytetrafluoroethylene (PTFE) (9002-84-0)	4.03E-01	1.65%	0.08%	surface	Direct data on fibres for the function 'water repellent' (Information provided by a textiles retailer) (generally referred to e.g. polymers and fluorocarbons) assumed referred to a dispersion of PTFE. The amount of components of the mixture were calculated considering complementary information from safety datasheets of a mixture with PTFE for coating[307] [308] (proxy)
		2,6,8-Trimethyl-4-Nonyloxypolyethyleneoxyethanol (60828-78-6)	2.20E-02	0.09%	<0.01%	surface	

[305] Avagyan, R., Luongo, G., Thorsén, G. et al. Benzothiazole, benzotriazole, and their derivates in clothing textiles—a potential source of environmental pollutants and human exposure. Environ Sci Pollut Res 22, 5842–5849 (2015). https://doi.org/10.1007/s11356-014-3691-0.

[306] Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (BPR).

[307] https://www.quintech.de/wp-content/uploads/2020/07/SDS-TeflonDISP30-2018-ENG.pdf. The source is consulted only for the purpose of obtaining information about the composition of the mixture. It is not intended as a proof of compliance with Annex II of REACH.

[308] https://www.inolub.com/pdf/Inolub%20WD%20SDS_Eng.pdf. The source is consulted only for the purpose of obtaining information about the composition of the mixture. It is not intended as a proof of compliance with Annex II of REACH.

Materials (m_i)	Function description	Functional chemicals (CAS number)	Mass (g)	Conc. In material $c_{BC,material}$ (% w/w)	Conc. in product $c_{BC,product}$ (% w/w)	Details (location)	Set-up for calculation (i.e. mass balance[301]/direct data on product) and sources
	Biocides	(benzothiazol-2-ylthio)methyl thiocyanate; TCMTB (21564-17-0)	1.24E-03	0.01%	<0.01%	surface	Direct data on product for PES cloth (assumed for all BASE CASE) (Avagyan et al., 2015)[309] The mentioned source is about benzothiazole derivative. For the Case Study, a derivative approved for use as active substance under BPR[310] is considered.
	Anti-felt/anti-shrink treatment (finishing) - oxidant treatment	Sodium hypochlorite (7681-52-9)	1.1	4.5%	0.22%	surface	Direct data on fibres. Input amount to process from BREF for textiles Table 8.45, referred to 'dichloroisocyanurate', amount on product for the function 'unshrinkage' for 'dichloroisocianuric' substance from Information provided by a textiles retailer data. For the Base Case substituted with 'sodium hypochlorite' assuming 1:1 mass ratio, since the latter is more representative for the worst case scenario - see testing on C1
	Anti-felt/anti-shrink treatment (finishing) - resin/polymer application	Polymer (PA) based resin with epichlorohydrin (no CAS found) (proxy with epichlorohydrin, CAS 106-89-8)[311]	5.49E-01	2.25%	0.11%	surface	Direct data on fibres. Input amount to process from BREF for textiles Table 8.45, referred to 'polymers'. Amount on product for the function 'unshrinkage' for 'polymers' substance from Information provided by a textiles retailer data
Cotton fibre	Natural polymer	Cellulose (9004-34-6)	171.47	82.65%	34.29%		Mass balance, net amount (without substances, both intentionally and non intentionally added) from the materials shares data
	Dyes	Direct Orange 62 (12222-38-7)	1.19E+01	5.76%	2.39%	surface	Mass balance, considering mass of input dye (Information provided by a textiles retailer), number of uses of bath equal to 1 for batch dyeing (Information provided by a textiles retailer) and the percentage of non-fixed dye discharged (Table 8.12 BREF for textiles, Euratex data)

[309] Avagyan, R., Luongo, G., Thorsén, G. et al. Benzothiazole, benzotriazole, and their derivates in clothing textiles—a potential source of environmental pollutants and human exposure. Environ Sci Pollut Res 22, 5842–5849 (2015). https://doi.org/10.1007/s11356-014-3691-0.

[310] Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (BPR).

[311] Not found a specific substance with CAS for this generic substance. This gap is discussed in the **Box 2**.

Materials (m_i)	Function description	Functional chemicals (CAS number)	Mass (g)	Conc. In material $c_{BC,material}$ (% w/w)	Conc. in product $c_{BC,product}$ (% w/w)	Details (location)	Set-up for calculation (i.e. mass balance[301]/direct data on product) and sources
	Fixers	Formaldehyde, reaction products with melamine (94645-56-4)	1.66	0.80%	0.33%	surface	Amount on fibres for the function 'fixers' (Information provided by a textiles retailer)
	Easy-care finishing agents	Hexa(methoxymethyl)melamine (3089-11-0)	1.87E+01	9%	3.73%	surface	Amount on fibres for the function 'no crease effect' (Information provided by a textiles retailer)
	Softener	Polysiloxane (161755-53-9)	1.87E+00	0.90%	0.37%	surface	Amount on fibres for the function 'softner' (Information provided by a textiles retailer)
	Water-repellent agents	Polytetrafluoroethylene (PTFE) (9002-84-0)	3.42E+00	1.65%	0.68%	surface	Direct data on fibres for the function 'water repellent' (Information provided by a textiles retailer) (generally referred to e.g. polymers and fluorocarbons) assumed referred to a dispersion of PTFE. The amount of components of the mixture were calculated considering complementary information from safety datasheets of a mixture with PTFE for coating[312] [313] (proxy)
		2,6,8-Trimethyl-4-Nonyloxypolyethyleneoxyethanol (60828-78-6)	1.87E-01	0.09%	0.04%	surface	
	Biocides	(benzothiazol-2-ylthio)methyl thiocyanate; TCMTB	1.06E-02	0.01%	<0.01%	surface	Direct data on product for PES cloth (assumed for all BASE CASE) (Avagyan et al., 2015)[314] The mentioned source is about benzothiazole derivative. For the

[312] https://www.quintech.de/wp-content/uploads/2020/07/SDS-TeflonDISP30-2018-ENG.pdf. The source is consulted only for the purpose of obtaining information about the composition of the mixture. It is not intended as a proof of compliance with Annex II of REACH.

[313] https://www.inolub.com/pdf/Inolub%20WD%20SDS_Eng.pdf. The source is consulted only for the purpose of obtaining information about the composition of the mixture. It is not intended as a proof of compliance with Annex II of REACH.

[314] Avagyan, R., Luongo, G., Thorsén, G. et al. Benzothiazole, benzotriazole, and their derivates in clothing textiles—a potential source of environmental pollutants and human exposure. Environ Sci Pollut Res 22, 5842–5849 (2015). https://doi.org/10.1007/s11356-014-3691-0.

Materials (m_i)	Function description	Functional chemicals (CAS number)	Mass (g)	Conc. In material $c_{BC,material}$ (% w/w)	Conc. in product $c_{BC,product}$ (% w/w)	Details (location)	Set-up for calculation (i.e. mass balance[301]/direct data on product) and sources
		(21564-17-0)					Case Study, a derivative approved for use as active substance under BPR[315] is considered.
Nylon 6.6, fossil fuel-based	Synthetic polymer	NYLON 6/66 (24993-04-2)	6.06	87.46%	1.21%		Mass balance, net amount (without substances, both intentionally and non intentionally added) from the materials shares data
	Dyes	Reactive Blue 72 (61968-93-2)	5.37E-01	7.76%	0.11%	surface	Mass balance, considering mass of input dye (BREF for textiles Table 4.71), number of uses of bath equal to 1 for batch dyeing (Information provided by a textiles retailer) and the percentage of non-fixed dye discharged (Table 2.16 BREF for textiles, Euratex data) (generally referred to reactive dyes)
	Water-repellent agents	Polytetrafluoroethylene (PTFE) (9002-84-0)	1.14E-01	1.65%	0.02%	surface	Direct data on fibres for the function 'water repellent' (Information provided by a textiles retailer) (generally referred to e.g. polymers and fluorocarbons) assumed referred to a dispersion of PTFE. The amount of components of the mixture were calculated considering complementary information from safety datasheets of a mixture with PTFE for coating (proxy)
		2,6,8-Trimethyl-4-Nonyloxypolyethyleneoxyethanol (60828-78-6)	6.23E-03	0.09%	<0.01%	surface	
	Biocides	(benzothiazol-2-ylthio)methyl thiocyanate; TCMTB (21564-17-0)	3.53E-04	0.01%	<0.01%	surface	Direct data on product for PES cloth (assumed for all BASE CASE) (Avagyan et al., 2015)[316] The mentioned source is about benzothiazole derivative. For the Case Study, a derivative approved for use as active substance under BPR[317] is considered.

[315] Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (BPR).

[316] Avagyan, R., Luongo, G., Thorsén, G. et al. Benzothiazole, benzotriazole, and their derivates in clothing textiles—a potential source of environmental pollutants and human exposure. Environ Sci Pollut Res 22, 5842–5849 (2015). https://doi.org/10.1007/s11356-014-3691-0.

[317] Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (BPR).

Materials (m_i)	Function description	Functional chemicals (CAS number)	Mass (g)	Conc. In material $c_{BC,material}$ (% w/w)	Conc. in product $c_{BC,product}$ (% w/w)	Details (location)	Set-up for calculation (i.e. mass balance[301]/direct data on product) and sources
Polyester	Synthetic polymer	Polyester (113669-95-7)	64.88	86.36%	12.98%		Mass balance, net amount (without substances, both intentionally and non intentionally added) from the materials shares data
	Dyes	Disperse Blue 35 (12222-75-2)	4.09	5.45%	0.82%	surface	Mass balance, considering mass of input standard dye (Table 4.81 BREF for textiles), number of uses of bath equal to 1 for batch dyeing (Information provided by a textiles retailer) and the percentage of non-fixed dye discharged (Table 2.16 BREF for textiles, Euratex data) (generally referred to disperse dyes)
	Water-repellent agents	Polytetrafluoroethylene (PTFE) (9002-84-0)	1.24E+00	1.65%	0.25%	surface	Direct data on fibres for the function 'water repellent' (Information provided by a textiles retailer) (generally referred to e.g. polymers and fluorocarbons) assumed referred to a dispersion of PTFE. The amount of components of the mixture were calculated considering complementary information from safety datasheets of a mixture with PTFE for coating (proxy)
		2,6,8-Trimethyl-4-Nonyloxypolyethyleneoxyethanol (60828-78-6)	6.76E-02	0.09%	0.01%	surface	
	Biocides	(benzothiazol-2-ylthio)methyl thiocyanate; TCMTB (21564-17-0)	3.83E-03	0.01%	<0.01%	surface	Direct data on product for PES cloth (assumed for all BASE CASE) (Avagyan et al., 2015)[318] The mentioned source is about benzothiazole derivative. For the Case Study, a derivative approved for use as active substance under BPR[319] is considered.
Polyethylene terephthalate (PET), recycled, semi-	Synthetic polymer	Polyethylene terephthalate (PET) (25038-59-9)	9.88	71.36%	1.98%		Mass balance, net amount (without substances, both intentionally and non intentionally added) from the materials shares data

[318] Avagyan, R., Luongo, G., Thorsén, G. et al. Benzothiazole, benzotriazole, and their derivates in clothing textiles—a potential source of environmental pollutants and human exposure. Environ Sci Pollut Res 22, 5842–5849 (2015). https://doi.org/10.1007/s11356-014-3691-0.

[319] Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (BPR).

Materials (m_i)	Function description	Functional chemicals (CAS number)	Mass (g)	Conc. In material $c_{BC,material}$ (% w/w)	Conc. in product $c_{BC,product}$ (% w/w)	Details (location)	Set-up for calculation (i.e. mass balance[301]/direct data on product) and sources
mechanical, post-consumer	Flame retardants (fibre production)	Decabromodiphenyl ethane (DBDPE) (84852-53-9)	2.08	15.00%	0.42%	matrix	Direct data on fibres (Page 384, BREF for textiles) (generally referred to flame retardants). It is supposed to be present in recycled PET because of possible use in the previous life cycle from different application[320]
	Dyes	Disperse Blue 35 (12222-75-2)	7.54E-01	5.45%	0.15%	surface	Mass balance, considering mass of input generic standard disperse dye (Table 4.81 BREF for textiles), number of uses of bath equal to 1 for batch dyeing (Information provided by a textiles retailer) and the percentage of non-fixed dye discharged (Table 2.16 BREF for textiles, Euratex data) (generally referred to disperse dyes)
	Water-repellent agents	Polytetrafluoroethylene (PTFE) (9002-84-0)	2.29E-01	1.65%	0.05%	surface	Direct data on fibres for the function 'water repellent' (Information provided by a textiles retailer) (generally referred to e.g. polymers and fluorocarbons) assumed referred to a dispersion of PTFE. The amount of components of the mixture were calculated considering complementary information from safety datasheets of a mixture with PTFE for coating (proxy)
		2,6,8-Trimethyl-4-Nonyloxypolyethyleneoxyethanol (60828-78-6)	1.25E-02	0.09%	<0.01%	surface	
	Biocides	(benzothiazol-2-ylthio)methyl thiocyanate; TCMTB (21564-17-0)	7.06E-04	0.01%	<0.01%	surface	Direct data on product for PES cloth (assumed for all BASE CASE) (Avagyan et al., 2015)[321] The mentioned source is about benzothiazole derivative. For the Case Study, a derivative approved for use as active substance under BPR[322] is considered.

320 United Nations Environment Programme and Secretariat of the Basel, Rotterdam and Stockholm Conventions (2023). Chemicals in plastics: a technical report. Geneva. https://www.unep.org/resources/report/chemicals-plastics-technical-report.

321 Avagyan, R., Luongo, G., Thorsén, G. et al. Benzothiazole, benzotriazole, and their derivates in clothing textiles—a potential source of environmental pollutants and human exposure. Environ Sci Pollut Res 22, 5842–5849 (2015). https://doi.org/10.1007/s11356-014-3691-0.

322 Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (BPR).

Materials (m_i)	Function description	Functional chemicals (CAS number)	Mass (g)	Conc. In material $c_{BC,material}$ (% w/w)	Conc. in product $c_{BC,product}$ (% w/w)	Details (location)	Set-up for calculation (i.e. mass balance[301]/direct data on product) and sources
Viscose fibre	Natural polymer	Cellulose (9004-34-6)	6.90	81.66%	1.38%		Mass balance, net amount (without substances, both intentionally and non intentionally added) from the materials shares data
	Dyes	Direct Orange 62 (12222-38-7)	4.87E-01	5.76%	0.10%	surface	Mass balance, considering mass of input dye for the function 'direct dye' (Information provided by a textiles retailer), number of uses of bath equal to 1 for batch dyeing (Information provided by a textiles retailer) and the percentage of non-fixed dye discharged (Table 8.12 BREF for textiles, Euratex data)
	Fixers	Formaldehyde, reaction products with melamine (94645-56-4)	6.76E-02	0.80%	0.01%	surface	Amount on fibres for the function 'fixers' (Information provided by a textiles retailer)
	Easy-care finishing agents	Hexa(methoxymethyl)mel amine (3089-11-0)	7.60E-01	9%	0.15%	surface	Amount on fibres for the function 'no crease effect' (Information provided by a textiles retailer)
	Water-repellent agents	Polytetrafluoroethylene (PTFE) (9002-84-0)	1.39E-01	1.65%	0.03%	surface	Direct data on fibres for the function 'water repellent' (Information provided by a textiles retailer) (generally referred to fluorocarbons) assumed referred to a dispersion of PTFE. The number of components of the mixture were calculated considering complementary information from safety datasheets of a mixture with PTFE for coating (proxy)
		2,6,8-Trimethyl-4-Nonyloxypolyethyleneoxyethanol (60828-78-6)	7.60E-03	0.09%	<0.01%	surface	

Materials (m_i)	Function description	Functional chemicals (CAS number)	Mass (g)	Conc. In material $c_{BC,material}$ (% w/w)	Conc. in product $c_{BC,product}$ (% w/w)	Details (location)	Set-up for calculation (i.e. mass balance[301]/direct data on product) and sources
	Biocides	(benzothiazol-2-ylthio)methyl thiocyanate; TCMTB (21564-17-0)	4.31E-04	0.01%	<0.01%	surface	Direct data on product for PES cloth (assumed for all BASE CASE) (Avagyan et al., 2015)[323] The mentioned source is about benzothiazole derivative. For the Case Study, a derivative approved for use as active substance under BPR[324] is considered.
	Delustering agent (fibre production)	Titanium dioxide (13463-67-7)	8.45E-02	1.00%	0.02%	matrix[325]	Direct data on material (Pinfloc, 2014)[326]
	Softner	Polysiloxane (161755-53-9)	7.60E-02	0.90%	0.02%	surface	Amount on fibres for the function 'softner' (Information provided by a textiles retailer)
Wool, sheep	Natural animal hair	Keratine (68238-35-7)	144.90	98.94%	28.98%		Mass balance, net amount (without substances, both intentionally and non-intentionally added) from the materials shares data
	Dyes	Reactive Blue 72 (61968-93-2)	1.14E+01	7.76%	2.27%	surface	Mass balance, considering mass of input dye (BREF FOR TEXTILES Table 4.71), number of uses of bath equal to 1 for batch dyeing (Information provided by a textiles retailer) and the percentage of non-fixed dye discharged (Table 2.16 BREF for textiles, Euratex data) (generally referred to reactive dyes)
	Water-repellent agents	Polytetrafluoroethylene (PTFE) (9002-84-0)	2.42E+00	1.65%	0.48%	surface	Direct data on product (Information provided by a textiles retailer) (generally referred to polymers and fluorocarbons) assumed referred to a dispersion of PTFE. The number of components of the mixture were calculated considering

323 Avagyan, R., Luongo, G., Thorsén, G. et al. Benzothiazole, benzotriazole, and their derivates in clothing textiles—a potential source of environmental pollutants and human exposure. Environ Sci Pollut Res 22, 5842–5849 (2015). https://doi.org/10.1007/s11356-014-3691-0.

324 Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (BPR)

325 The pigment is reported in SDS to be spun-dyed. i.e. "the dye is incorporated in the synthetic fibre during its production" (BREF FOR TEXTILES).

326 Pinfloc, Safety Data Sheet of Viscose, 2014, https://www.pinfloc.com/PDF/PIN-SafetyDataSheet/englisch/SafetyDataSheet-Viscose-ENG.pdf. The source is consulted only for the purpose of obtaining information about the composition of the mixture. It is not intended as a proof of compliance with Annex II of REACH.

Materials (m_i)	Function description	Functional chemicals (CAS number)	Mass (g)	Conc. In material $c_{BC,material}$ (% w/w)	Conc. in product $c_{BC,product}$ (% w/w)	Details (location)	Set-up for calculation (i.e. mass balance[301]/direct data on product) and sources
		2,6,8-Trimethyl-4-Nonyloxypolyethyleneoxyethanol (60828-78-6)	1.32E-01	0.09%	<0.01%	surface	complementary information from safety datasheets of a mixture with PTFE for coating (proxy)
	Biocides	(benzothiazol-2-ylthio)methyl thiocyanate; TCMTB (21564-17-0)	7.47E-03	0.01%	<0.01%	surface	Direct data on product for PES cloth (assumed for all BASE CASE) (Avagyan et al., 2015)[327] The mentioned source is about benzothiazole derivative. For the Case Study, a derivative approved for use as active substance under BPR[328] is considered.
	Anti-felt/anti-shrink treatment (finishing) - oxidant treatment	Sodium hypochlorite (7681-52-9)	6.59	4.50%	1.32%	surface	Direct data on fibres. Input amount to process from BREF for textiles Table 8.45, referred to 'dichloroisocyanurate', amount on product for the function 'unshrinkage' for 'dichloroisocianuric' substance from Information provided by a textiles retailer data. For the Base Case substituted with 'sodium hypochlorite' assuming 1:1 mass ratio, since the latter is more representative for the worst-case scenario**.**
	Anti-felt/anti-shrink treatment (finishing) - resin/polymer application	Polymer based resin with epichlorohydrin (no CAS found) (proxy with epichlorohydrin, CAS 106-89-8)	3.30	2.25%	0.66%	surface	Direct data on fibres. Input amount to process from BREF for textiles Table 8.45, referred to 'polymers. Amount on product for the function 'unshrinkage' for 'polymers' substance from Information provided by a textiles retailer data

Source: JRC's own elaboration.

[327] Avagyan, R., Luongo, G., Thorsén, G. et al. Benzothiazole, benzotriazole, and their derivates in clothing textiles—a potential source of environmental pollutants and human exposure. Environ Sci Pollut Res 22, 5842–5849 (2015). https://doi.org/10.1007/s11356-014-3691-0.

[328] Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (BPR).

Box 6. Comments and lessons learnt from the testing on Section A: Preliminary steps for the method (focus on functional substances in the product).

A challenge of this Case Study is that for one function (anti-felt treatment) **no specific substance with a CAS number was identified** (the BREF for textiles mentions a generic one, i.e. substance 'polymer-based resin with epichlorohydrin'), and thus epichlorohydrin was considered as a **proxy**. This approach was chosen as, in general, when no specific information about mixture composition was available, the substance composing the mixture with available information was assumed to be representative for all the mixtures. In addition, the information available did not allow to understand whether the polymer-based resin is actually a mixture, or whether it is a substance identified with a CAS number. Limitations on the availability of CAS number may also be present, due to the fact that CAS numbers are usually assigned to pure chemical substances, with the exclusion of mixtures, commercial products, or non-chemical entities (for example living organisms, minerals, or elements). In some cases, a chemical name may have more than one CAS Registry Number (or other identifier) associated with it due to the chemical's various forms.

It is worth mentioning that the approach adopted in **data modelling**, i.e. the set-up used in the calculation of the concentrations of substances in products, if not consistent, may lead to different treatments of substances that are not supported by actual differences in the function and in the technologies used for their application to the product. It is suggested to apply the same set-up in the calculation, at least for substances that fulfil the same function.

Moreover, when several options of data modelling are available, the set-up for calculation based on direct data on fibres is preferable. The % w/w for Disperse Blue 35 and Reactive Blue 72 (**Table 26**) slightly exceed the upper value of the typical range for dye content (up to 6%, depending on the dye and on the fibre type, according to Information provided by a textiles retailer).

Non-intentionally added substances and substances along the life cycle stages

The aim of the testing on this section is to provide an overview, quantitative to the extent possible, with regard to the substances utilised and emitted along the life cycle of the Base Case. In particular, the aim is to improve the substance composition of the Base Case with the information on non-intentionally added substances (NIAS), as well as to complete the inventory, to the extent possible, as regards emissions along the life cycle. The whole value chain is considered in this assessment, encompassing primary supply chain and use phases.

For what concerns the primary supply chain the following actions were performed:

- analysis of functional substances not present in the Base Case (process-related emissions);
- analysis of substances that are used as process auxiliaries and which may lead to their presence in the Base Case (as non-intentionally added substances) or not (process-related emissions).

For what concerns the product use stage, in the present Case Study the use of auxiliaries, i.e. substances used in laundry detergents during the domestic washing of the textile, were not included since the manufacturing stage was considered as the major sources of chemicals. This choice is not a suggestion for a cut-off to exclude such substances but rather reflects a choice to simplify the Case Study. Nevertheless, leachate of functional chemicals and impurities (deriving from the primary supply chain) during laundry were included.

A global value chain is considered for the primary supply chain of the Base Case, since it is the typical setting for this product group (see analysis in point 1 “Collection schemes and waste flows” below), while the use phase is considered to be based in the EU, given that ESPR applies to products placed on the Union market.

The BREF for textiles provides in-depth information about the manufacturing stage (i.e. the production of the main product), while the raw material acquisition (for fibre production) and pre-processing are considered to a lesser extent. This gap is reflected also in the substances identified in the present Case Study.

The inventory with the alternative substances for each function was compiled and single substances per function were selected and quantified for the Base Case.

The steps to define the Base Case are reported in **Figure 13**. On the left side of the figure all inputs are reported (in green columns), where materials and related substances considered in each stage are listed. In the centre, in blue, the life cycle stages are reported, detailing for each life cycle stage the steps that were considered.

Moving to the right side of **Figure 13**, the column in yellow reports the substances that are present in the materials/product (starting from the constituent materials, i.e. intermediate product in **Figure 13**, to the product itself after the manufacturing phase and to the waste after use phase). Some substances are acknowledged to be retained on the fibres but washed away during the manufacturing process (e.g. pesticides for wool, solvents for viscose), thus these substances are not expected to be found in the final product. Other impurities may arise on the fibres during the manufacturing process.

On the right side, the columns in orange represent the emissions to the environment (to air, water and soil). The flows of chemicals in the manufacturing stage in **Figure 13** are based on the information provided in the BREF for textiles, while the emissions in the use phase are based on other literature sources and is reported in **Table 29** and **Table 30**. Additional types of manufacturing processes were considered compared to those reported in data sources for the LCA inventory. For example, different types of dyes were considered in the Case Study for the various materials used, since they were assumed to be representative for different materials in terms of chemicals according to other literature findings.

In **Table 27** the non-intentionally added substances that could be present in the Base Case are summarised, while in **Table 28** their concentrations in the Base Case are reported (c_{BC}). No cut-off threshold was set in this Case Study to map non-intentionally added substances in the Base Case, i.e. all the substances that were reported in the literature sources as "traces" or "impurities" were included.

The amount of input substances and of emissions during the manufacturing of the Base Case and the use stage (a_{LC}) are reported, too, in **Table 29** and **Table 30**. Since no specific data were found for emissions during the use stage for almost any non-intentionally added substances, under the worst-case scenario these chemicals) are assumed to not be washed away during the use stage, but instead they would be found in the waste product (Textile companies webinar, 2021[329]).

Other limitations and assumptions to be highlighted are as follows:

- Mixtures applied in specific treatments might be reported according to the function of the components, as done in the BREF. Unless specific information is reported in the BREF or in safety datasheets to allow a more precise representation of the mixture, the substances reported can represent i) the mixture components with the higher or ii) the mixture components that were highlighted as most hazardous.
- For simplification, substances that may be added during the transport of raw materials and the transport in the distribution phase are not considered.
- Air and water emissions from the manufacturing and the use stages are assumed to happen into air and freshwater, after exhaust air and wastewater treatment. In the present study, considering that the primary supply chain is located mainly in third countries, a worst-case scenario is assumed and the effect of treatment process is not taken into account (i.e. the chemicals are considered to be released into the environment un-degraded or un-abated).
- The identification of emissions of degraded compounds was performed only in limited cases, where specific data were available. The BREF for textiles reports emission factors of organic carbon as a function of the temperature and duration of the test. For additional information see **Table 31**.
- Nonylphenol ethoxylates (NPEOs), a group of lipophilic compounds, are acknowledged as often-found in wool because of the high lipid content of this type of fibre. However, some test reports indicate the presence of non-intentionally added NPEOs also on synthetic fibres and cotton (Brigden et al., 2012[330]; Textile companies webinar, 2021[331]), thus NPEOs are reported in **Table 28** for all the materials.
- For emissions of non-intentionally added substances to the product during the use stage (**Table 30**) no specific data were found for most substances (except for NPEOs and Perfluorooctanoic acid (PFOA)) Thus, the worst case assumption is made in those cases, i.e. NIAS in the product are not washed away during the use stage and they are all found in waste product.

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329 Webinar, Collaborative study on chemicals in recycled textiles, October 2021, https://www.naturvardsverket.se/4af32a/contentassets/be04327b5a874955a5402d4f663d1632/webinar-collaborative-study-chemicals-recycled-textiles-hm-ikea.pdf.

330 Brigden, K., Santillo, D., Johnston, P., Greenpeace, Nonylphenol ethoxylates (NPEs) in textile products, and their release through laundering, Greenpeace Research Laboratories Technical Report 01/2012, https://www.greenpeace.org/static/planet4-international-stateless/2012/03/806ceff8-dirty_laundry_product_testing_technical_report_01-2012.pdf.

331 Webinar, Collaborative study on chemicals in recycled textiles, October 2021, https://www.naturvardsverket.se/4af32a/contentassets/be04327b5a874955a5402d4f663d1632/webinar-collaborative-study-chemicals-recycled-textiles-hm-ikea.pdf.

— For emissions occurring from the landfilling of waste, it is assumed that the substances entering the landfill as part of the waste, are the same substances that can leach out from the landfill (no degradation products are considered). The mass leaching out corresponds to the total amount of substance, following a worst-case scenario. An alternative approach to estimate such releases can be the use of the default release rates from ECHA, 2012[332].

[332] European Chemicals Agency (ECHA), 2012, Guidance on information requirements and chemical safety assessment Chapter R.18: Exposure scenario building and environmental release estimation for the waste life stage, https://echa.europa.eu/documents/10162/17224/r18_v2_final_en.pdf/e2d1b339-f7ca-4dba-8bdc-76e25b1c668c.

Figure 13. Life cycle stages of the Base Case, with input, output substances and substances that remain (yellow column) on the Base Case.

MATERIALS	INPUT SUBSTANCES	LIFE CYCLE STAGES	INTERMEDIATE PRODUCT/ FINAL PRODUCT/ WASTE/ RECYCLATE	EMISSIONS		
			Intermediate product (fibres/yarn)	air (exhaust air)	Freshwater/groundwater	soil
• Raw wool, sheep, • Raw cashmere	Diazinon - *Pesticide*	Agricultural phase (GLO)	Diazinon (I)			Diazinon
Raw cotton	Chlorpyrifos - *Pesticide*		Chlorpyrifos (I)			Chlorpyrifos
Viscose	• Carbon disulphide - *Solvent* • Zinc sulphate - *Acid agent* • Sodium hydroxide – *solvent* • Sulphuric acid - *solvent* • Titanium dioxide – *delustering agent*	Fibres manufacturing (GLO)	• Zinc sulphate (I) • Carbon disulphide (I) • Titanium dioxide (F)	Sulfur (sum of carbon disulphide and hydrogen sulfide)	• Zinc sulphate • Sulphate ion (from sulphuric acid) • Adsorbable organically bound halogens (AOXs) • Chemical Oxygen Demand (COD)	
Acrylic	N,N - Dimethylacetamide *Solvent*		N,N – Dimethylacetamide (I)	N,N - Dimethylacetamide	N,N - Dimethylacetamide	
• Cotton, • Viscose, • Wool, • Cashmere	• Mineral oil - *Lubricant* • Naphthalene (from mineral oil) • Nonylphenol ethoxylates (NPEOs) – *emulsifier* • Imidazole - *biocide*		• Mineral oil • Naphthalene (I) • Nonylphenol ethoxylates (NPEOs) (I) • Imidazole (I)			
• Polyester, • Polyethylene terephthalate (PET), recycled, semi-mechanical, post-consumer, • Nylon 6.6, fossil fuel-based	• Antimony trioxide – *Catalyst* (from fibres) • Decabromodiphenyl ethane (DBDPE) (for recycled PET only) *flame retardant*		• Benzaldehyde (As VOC) (for recycled PET) (I) • Decabromodiphenyl ethane (DBDPE) (for recycled PET) (F) • Antimony trioxide (I)		Antimony trioxide	
• Cotton, • Viscose, • Wool, • Cashmere	Nonylphenol ethoxylates (NPEOs) *surfactant*	Scouring (GLO)	Nonylphenol ethoxylates (NPEOs) (I)		• Diazinon • Chlorpyrifos • Zinc sulphate • Carbon disulphide • Nonylphenol ethoxylates (NPEOs) • Nonylphenol (NP)* • Mineral oil • Naphthalene • Imidazole	
All	• Mineral oil - *Lubricant* • Naphthalene (from mineral oil) • Nonylphenol ethoxylates (NPEOs) – *emulsifier* • Imidazole - *biocide*	Dry spinning (GLO)	• Mineral oil • Naphthalene (I) • Nonylphenol ethoxylates (NPEOs) (I) • Imidazole (I)			
All	• Mineral oil - *Lubricant (for needles)* • Naphthalene (from mineral oil)	Knitting (GLO)	• Mineral oil • Naphthalene (I)			• Mineral oil • Naphthalene
• Viscose, • Wool, • Cashmere • Polyester, • Polyethylene terephthalate (PET), recycled, semi-mechanical, post-consumer, • Nylon 6.6, fossil fuel-based		*Heat setting*		Volatile organic coumpounds (VOC)**		
All	• Nonylphenol ethoxylates (NPEOs) - *surfactant* • Ethylenediaminetetraacetic acid (EDTA) - *complexing*	Washing	Nonylphenol ethoxylates (NPEOs) (I)		• Nonylphenol ethoxylates (NPEOs) • Nonylphenol (NP)* • Mineral oil • Naphthalene • Imidazole • Ethylenediaminetetraacetic acid (EDTA)	
Cotton	• Sodium hypochlorite *oxidant agent* • Nonylphenol ethoxylates (NPEOs) *surfactant* • Sodium hydroxide - *alkaline*	Bleaching (GLO)	Nonylphenol ethoxylates (NPEOs) (I)		• Sodium hypochlorite • Adsorbable organically bound halogens (AOXs, e.g. trichloromethane)* • Sodium hydroxide • Nonylphenol ethoxylates (NPEOs) • Nonylphenol (NP)*	
• Wool • Cashmere	• Hydrogen peroxide *oxidant agent* • Sodium dithionite – *reductive agent* • Ethylenediaminetetraacetic acid (EDTA) - *stabilizer* • Nonylphenol ethoxylates (NPEOs) - *surfactant*	Bleaching (GLO)	Nonylphenol ethoxylates (NPEOs) (I)		• Hydrogen peroxide • Sodium dithionite • Ethylenediaminetetraacetic acid (EDTA) • Complexes with metals* • Nonylphenol ethoxylates (NPEOs) • Nonylphenol (NP)*	
• Cotton • Viscose	• Direct Orange 62 - *Dye* • Sodium chloride - *Salt* • Formaldehyde, reaction products with melamine – *after-treatment* • Sodium carbonate – *alkaline* • Nonylphenol ethoxylates (NPEOs) - *wetting agent* • Polyvinylpyrrolidone - *levelling agent*	Direct dyeing (batch) (GLO)	• Direct Orange 62 (F) • Formaldehyde, reaction products with melamine (F) • Polyvinylpyrrolidone (F) • Nonylphenol ethoxylates (NPEOs) (I)		• Direct Orange 62 • Sodium chloride • Formaldehyde, reaction products with melamine • Sodium carbonate • Polyvinylpyrrolidone • Nonylphenol ethoxylates (NPEOs) • Nonylphenol (NP)*	

MATERIALS	INPUT SUBSTANCES	LIFE CYCLE STAGES	INTERMEDIATE PRODUCT/ FINAL PRODUCT/ WASTE/ RECYCLATE	EMISSIONS		
• Polyester, • Polyethylene terephthalate (PET), recycled, semi-mechanical, post-consumer, • Acrylic fibres	• Disperse Blue 35 - *Dye* • 1,2,4, trichlorobenzene - *Carrier* • Sodium chloride - *Salt* • Acetic acid – *pH adjuster* • Lauryl amine ethoxylated - *levelling agent* • Nonylphenol ethoxylates (NPEOs) – *detergent/dispersing agent*	**Disperse dyeing (batch) (GLO)**	• Disperse Blue 35 (F) • 1,2,4, trichlorobenzene (I) • Monomers and cyclic dimers (I)		• Disperse Blue 35 • 1,2,4, trichlorobenzene • Sodium chloride • Acetic acid • Lauryl amine ethoxylated • Chemical oxygen demand (COD)* • Nonylphenol ethoxylates (NPEOs) • Nonylphenol (NP)*	
• Wool, • Cashmere, • Nylon 6.6, fossil fuel-based	• Reactive Blue 72 - *Dye* • Sodium chloride - *Salt* • Acetic acid – *pH adjuster* • Lauryl amine ethoxylated - *levelling agent* • Ammonia – *washing agent*	**Reactive dyeing (batch) (GLO)**	• Reactive Blue 72 (F) • Copper (I)	Ammonia*	• Reactive Blue 72 • Copper (from Reactive Blue 72) • Sodium chloride • Acetic acid • Lauryl amine ethoxylated • Chemical oxygen demand (COD)* • Ammonia	
• Cotton • Viscose	• Hexa(methoxymethyl)melamine - *Easy care* • Ammonium sulfate – *catalyst* • Polysiloxane - *softner*	**Finishing (easy care) (GLO)**	• Hexa(methoxymethyl)melamine (F) • Polysiloxane (F)	• Formaldehyde • Methanol • Ammonia*	• Hexa(methoxymethyl) melamine • Ammonium sulfate • Polysiloxane	
• Wool, • Cashmere	• Sodium hypochlorite- *Oxidant treatment* • Sodium bisulphite – *anti-chlorine treatment* • Acetic acid – *pH adjuster* • Nonylphenol ethoxylates (NPEOs) - *detergent* • Polymer (PA) based resin with epichlorohydrin - *Resin/polymer*	**Finishing (anti-felt/anti-shrink treatment) (GLO)**	• Sodium hypochlorite (F) • Polymer (PA) based resin with epichlorohydrin (F) • Nonylphenol ethoxylates (NPEOs) (I)		• Sodium hypochlorite- *Oxidant treatment* • Sodium bisulphite – *anti-chlorine treatment* • Acetic acid – *pH adjuster* • Nonylphenol ethoxylates (NPEOs) • Nonylphenol (NP)* • Polymer (PA) based resin with epichlorohydrin - *Resin/polymer* • Adsorbable organically bound halogens (AOXs)*	
All	• Polytetrafluoro ethylene (PTFE) - *Water-repellent* • Pentadecafluorooctanoic Acid (PFOA) *(from PTFE)* • 2-(Thiocyanomethylthio)benzothiazole – *Biocide*	**Finishing (water repellent and biocide) (GLO)**	• Polytetrafluoro ethylene (PTFE) (F) • Pentadecafluorooctanoic Acid (PFOA) (I) • 2-(Thiocyanomethylthio)benzothiazole (F)		• Polytetrafluoro ethylene (PTFE) • Pentadecafluorooctanoic Acid (PFOA)	
		Drying (GLO)		• Polychlorinated dibenzodioxins/ dibenzofurans (PCDD/Fs)* • Volatile organic coumpounds (VOC)* • N,N – Dimethylacetamide • Ammonia*		
		Final product (BC)				
All		**Domestic Washing (EU)**	*no added chemicals (hp)*		Micro-fibres, Disperse Blue 35, Reactive Blue 72, Direct Orange 62, Sodium hypochlorite, Polymer (PA) based resin with epichlorohydrin, Hexa(methoxymethyl)melamine, Formaldehyde, reaction products with melamine, Polysiloxane, Polytetrafluoro ethylene (PTFE), Pentadecafluorooctanoic Acid (PFOA), 2-(Thiocyanomethylthio)benzothiazole, Nonylphenol ethoxylates (NPEOs), Nonylphenol (NP)*, Adsorbable organically bound halogens (AOXs)*	
		Post-consumer waste				
All		**Landfill (GLO)**			Disperse Blue 35, Reactive Blue 72, Direct Orange 62, Titanium dioxide, 2-(Thiocyanomethylthio)benzothiazole, Decabromodiphenyl ethane (DBDPE), Polytetrafluoro ethylene (PTFE), Pentadecafluorooctanoic Acid (PFOA), Copper, Mineral oil, Naphthalene, Benzaldehyde, 1,2,4, trichlorobenzene, N,N – Dimethylacetamide, Monomers and cyclic dimers Antimony trioxide	
All		**Incineration (GLO)**		• Polychlorinated dibenzodioxins/ dibenzofurans (PCDD/Fs) • Carbon monoxide • Nitrogen oxides • Sulphur dioxide • Hydrogen chloride • Particulates	Polychlorinated dibenzodioxins/ dibenzofurans (PCDD/Fs) *(fly ashes at the filter)*	
All		**Mechanical recycling (EU)**	Nonylphenol ethoxylates (NPEOs) (I)	*no emissions*		
		Recyclate				

Source: JRC's own elaboration.

Note: (GLO) indicates a global value chain, (EU) indicates that the stage occurs in the European Union. (F) means "functional substance", (I) means "NIAS". Chemicals marked with * have not been quantified because of lack of data for the authors knowledge (see **Table 31)**. "Heat setting process" in grey font indicates that the process was added in the Case Study compared to the available data sources. NPEOs are restricted under REACH (entry 46 and 46a Annex VII).

Table 27. List of possible non-intentionally added substances to the Base Case.

NIAS on the BC	CAS	Type	Origin/function	Process	Materials	Source to confirm the presence on the BC
Nonylphenol ethoxylates (NPEOs)	9016-45-9	Impurity (carry-over of auxiliary substance)	Surfactant, detergent	Scouring, spinning (in fibres manufacturing) and as dry spinning, washing, bleaching, direct dyeing, finishing (anti felt)	all	Brigden et al., 2012[333]; Textile companies webinar, H&M, IKEA, 2021[334]
Naphthalene	91-20-3	Impurity (in raw material)	Lubricant (mineral oil)	Spinning fibre/yarn, knitting	all	Textile companies webinar, H&M, IKEA, 2021; AFIRM, 2021[335]
White mineral oil	8042-47-5	Impurity (carry-over of auxiliary substance)	Lubricant	Spinning (in fibres manufacturing) and as dry spinning, knitting	all	AFIRM, 2021 (related to polycyclic hydrocarbon aromatic (PAH) impurity and assumed for lubricant, where PAH may be present, as well)
Benzaldehyde	100-52-7	Breakdown product	Raw material	Wear and recycling	recycled PET	Dutra et al., 2011[336] (related to food packaging, no information available about persistence on product after washings). In general VOCs due to polymer degradation are mentioned also in Duhoux et al., 2021[37]
1,2,4 – trichlorobenzene	120-82-1	Impurity (carry-over of auxiliary substance)	Carrier	Dyeing	PES, recycled PET, acrylic	BREF for textiles (page 700)[337]; Textile companies webinar, H&M, IKEA, 2021
Antimony trioxide	1309-64-4	Functional chemical that, during dyeing, arises from the matrix to the	Catalyst	Raw material production	PES, recycled PET, nylon	Rujido-Santos et al., 2022[338]; BREF for textiles (Table 4.12); Brigden et al., 2014[339]

333 Brigden, K., Santillo, D., Johnston, P., Greenpeace, Nonylphenol ethoxylates (NPEs) in textile products, and their release through laundering, Greenpeace Research Laboratories Technical Report 01/2012, https://www.greenpeace.org/static/planet4-international-stateless/2012/03/806ceff8-dirty_laundry_product_testing_technical_report_01-2012.pdf.

334 Webinar, Collaborative study on chemicals in recycled textiles, October 2021, https://www.naturvardsverket.se/4af32a/contentassets/be04327b5a874955a5402d4f663d1632/webinar-collaborative-study-chemicals-recycled-textiles-hm-ikea.pdf.

335 AFIRM Group, POLYCYCLIC AROMATIC HYDROCARBONS (PAHs), Chemical Information Sheet Version 2.0, March 2021 https://afirm-group.com/wp-content/uploads/2021/07/afirm_polycyclic_aromatic_hydrocarbons_v2.pdf.

336 Dutra, C., Pezo, D., de Alvarenga Freire, M. T., Nerín, C., Reyes Reyes, F. G., Determination of volatile organic compounds in recycled polyethylene terephthalate and high-density polyethylene by headspace solid phase microextraction gas chromatography mass spectrometry to evaluate the efficiency of recycling processes, Journal of Chromatography A, Volume 1218, Issue 10, 2011, Pages 1319-1330, ISSN 0021-9673, https://doi.org/10.1016/j.chroma.2010.12.099.

337 Roth, J., Zerger, B., De Geeter, D., Gómez Benavides, J., Roudier, S., Best Available Techniques (BAT) Reference Document for the Textiles Industry, Publications Office of the European Union, Luxembourg, 2023, doi:10.2760/355887, JRC 131874.

338 Rujido-Santos I, Herbello-Hermelo P, Barciela-Alonso MC, Bermejo-Barrera P, Moreda-Piñeiro A. Metal Content in Textile and (Nano)Textile Products. International Journal of Environmental Research and Public Health. 2022; 19(2):944. https://doi.org/10.3390/ijerph19020944.

339 Brigden, K., Santillo, D., Hetherington, M., Wang, S., Johnston, P., Greenpeace, Hazardous chemicals in branded luxury textile products on sale during 2013, Greenpeace Research Laboratories Technical Report 01/2012, https://www.greenpeace.to/greenpeace/wp-content/uploads/2014/02/Technical-Report-01-2014.pdf.

NIAS on the BC	CAS	Type	Origin/function	Process	Materials	Source to confirm the presence on the BC
		surface of fibres (becoming a breakdown product)				
Cyclic trimers of ethylene terephthalate	7441-32-9	Impurity (in raw material)	Raw material	Raw material production	PES, recycled PET, nylon	BREF for textiles (page 16) (it is supposed to remain on product after washings because it has a low solubility)
N,N-dimethylacetamide	127-19-5	Impurity (leftover auxiliary substance)	Solvent	Spinning in fibre	acrylic	ECHA, 2011[340], BREF for textiles (for residual content on fibres)
Copper - free metal impurity - not bound in the colourant	7440-50-8	Impurity (1- in raw materials, 2- as leftover of auxiliary substances)	Reactive dye (1) / catalyst for the manufacturing of the dye (2)	Raw material production	wool, cashmere, nylon	Rujido-Santos et al., 2022; ETAD, 2017[341]; BREF for textiles (page 85-86); Heens and Eliesen, 2023[342]
Pentadecafluorooctanoic Acid (PFOA)	335-67-1	Impurity (in raw material)	Raw material (PTFE)	Raw material production	all	Amec Foster Wheeler, 2020[343]; RI.SE, 2019[344] (referred to test material 16 - Mixed garments, WO/other fibres; van der Veen et al., 2022[345] (referred to outdoor clothing, PES containing)

Source: JRC's own elaboration.

[340] ANNEX XV – IDENTIFICATION OF N,N-DIMETHYLACETAMIDE (DMAC) AS SVHC, 2011, https://echa.europa.eu/documents/10162/17232/svhc_axvrep_echa_cmr_dmac_20110829_en.pdf/11fc0850-0f0a-4dbe-9caa-5f7c01dd4dfe.

[341] Ecological and Toxicological Association of Dyes and Organic Pigments Manufacturers (ETAD), ETAD threshold limits for impurities in dyes used in textile/leather applications (update 2017); https://etad.com/wp-content/uploads/ETAD-mandatory-limits-for-impurities-in-dyes_Rev-2017.pdf.

[342] Heens, F., Eliesen, G., Textile recycling in the Netherlands, Considerations for ensuring chemical product safety, Rijksinstituut voor Volksgezondheid en Milieu (RIVM), 2023, https://www.rivm.nl/publicaties/textile-recycling-in-netherlands-considerations-for-ensuring-chemical-product-safety#:~:text=Textile%20products%20must%20contain%20at%20least%2030%20percent,in%20consumer%20textile%20products%2C%20including%20plasticisers%20for%20prints.

[343] Amec Foster Wheeler Environment & Infrastructure GmbH (now part of Wood), The use of PFAS and fluorine-free alternatives in textiles, upholstry, carpets, leather and apparel, 2020, https://saicmknowledge.org/sites/default/files/resources/pfas_in_textiles_final_report_en.pdf.

[344] Research Institute of Sweden (RI.SE), REPORT Results of analyses for Classification and risk assessment of textiles for material recycling – Funded by Vinnova 2017- 2019, https://www.ri.se/sites/default/files/2020-11/Classification%20and%20risk%20assessment_analytical%20results.pdf.

[345] Ike van der Veen, Steffen Schellenberger, Anne-Charlotte Hanning, Ann Stare, Jacob de Boer, Jana M. Weiss, and Pim E. G. Leonards, Fate of Per- and Polyfluoroalkyl Substances from Durable Water-Repellent Clothing during Use, Environmental Science & Technology 2022 56 (9), 5886-5897, DOI: 10.1021/acs.est.1c07876.

Table 28. Non-intentionally added substances and their concentrations in the Base Case (c_{BC}).

Material	NIAS on the BC	CAS	Mass (g)	Concentration in material $c_{BC,material}$ (%)	Concentration in product $c_{BC,product}$ (%)	Set-up for calculation (i.e. mass balance/direct data on product) and sources
Acrylic fibres	Nonyl phenol ethoxylates (NPEOs)	9016-45-9	1.54E-03	0.01%	<0.01%	Direct data on product (Brigden et al., 2012[346]) – blend cotton/PE taken as reference for whole product. The final amount is then shared among the materials depending on the manufacturing processes where NPEOs were used
	White mineral oil	8042-47-5	5.48E-02	0.32%	0.01%	Based on direct data on product (Li et al., 2016)[347] for naphthalene– coated denim fabric taken as reference for whole base case, and considering that naphthalene may be up to 1.5% of mineral oil (ECHA, 2022)[348]
	Polycyclic aromatic hydrocarbons (PAH) e.g. naphthalene	91-20-3	3.99E-04	<0.01%	<0.01%	Direct data on product (Li et al., 2016) – coated denim fabric taken as reference for whole base case
	Pentadecafluorooctanoic Acid (PFOA)	335-67-1	7.19E-09	<0.01%	<0.01%	Concentration[349] in PTFE (Amec Foster Wheeler, [2020]) [350]
	1,2,4 - trichlorobenzene	120-82-1	5.93E-01	3.42%	0.12%	Mass balance, considering mass of input carrier (BREF for textiles)[351], water consumption (BREF for textiles), number of uses of bath equal to 1 for batch dyeing (Information provided by a textiles retailer) and the percentage of non-fixed carrier (water emissions) (BREF for textiles)

346 Brigden, K., Santillo, D., Johnston, P., Greenpeace, Nonylphenol ethoxylates (NPEs) in textile products, and their release through laundering, Greenpeace Research Laboratories Technical Report 01/2012, https://www.greenpeace.org/static/planet4-international-stateless/2012/03/806ceff8-dirty_laundry_product_testing_technical_report_01-2012.pdf.

347 Li X, Yang Y, Yang X, Li J, Li S, Tang S. Determination of Polycyclic Aromatic Hydrocarbons in Textiles by Gas Chromatography-Mass Spectrometry. AATCC Journal of Research. 2016;3(6):6-11. doi:10.14504/ajr.3.6.2.

348 ECHA Scientific report for evaluation of limit values for polycyclic aromatic hydrocarbons at the workplace Prepared by the European Chemicals Agency, 2022, https://echa.europa.eu/documents/10162/1b3bc755-ff8d-dd58-4b70-fc7329303b24

349 Note: the concentration was set according to the exemption as in Commission Delegated Regulation (EU) 2020/784 of 8 April 2020 amending Annex I to Regulation (EU) 2019/1021 of the European Parliament and of the Council as regards the listing of perfluorooctanoic acid (PFOA), its salts and PFOA-related compounds, OJ L 188I, 15.6.2020, p. 1–3

350 Amec Foster Wheeler Environment & Infrastructure GmbH (now part of Wood), The use of PFAS and fluorine-free alternatives in textiles, upholstry, carpets, leather and apparel, 2020, https://saicmknowledge.org/sites/default/files/resources/pfas_in_textiles_final_report_en.pdf.

351 Note: according to BREF FOR TEXTILES "Typical carrier formulations contain 60 – 80 % of active substance and 10 – 30 % of emulsifier and sometimes a small percentage of solvent". However, the data available in the BREF FOR TEXTILES are related to the active substance only (benzylbenzoate -based carriers, readily biodegradable substance, considered as a proxy, i.e. the same upper value of the range concentration is assumed for 1,2,4 – trichlorobenzene. The same value is confirmed also by Information provided by a textiles retailer data for chlorinated-based carriers).

Material	NIAS on the BC	CAS	Mass (g)	Concentration in material $C_{BC,material}$ (%)	Concentration in product $C_{BC,product}$ (%)	Set-up for calculation (i.e. mass balance/direct data on product) and sources
	N,N-dimethylacetamide	127-19-5	1.72E-05	< 0.01%	< 0.01%	< Detection limit (LOD)[352] of GC-MS[353]
Cashmere	Nonyl phenol ethoxylates (NPEOs)	9016-45-9	1.13E-02	0.05%	<0.01%	Direct data on product (Brigden et al., 2012) – blend cotton/PE taken as reference for whole product. The final amount is then shared among the materials depending on the manufacturing processes where NPEOs were used
	White mineral oil	8042-47-5	7.72E-02	0.32%	0.02%	Based on direct data on product (Li et al., 2016)[354] for naphthalene– coated denim fabric taken as reference for whole base case, and considering that naphthalene may be up to 1.5% of mineral oil (ECHA, 2022)[355]
	Polycyclic aromatic hydrocarbons (PAH) e.g. naphthalene	91-20-3	5.61E-04	<0.01%	<0.01%	Direct data on product (Li et al., 2016) – coated denim fabric taken as reference for whole base case
	1,2,4 - trichlorobenzene	120-82-1	8.35E-01	3.42%	0.17%	Mass balance, considering mass of input carrier (BREF for textiles), water consumption (BREF for textiles), number of uses of bath equal to 1 for batch dyeing (Information provided by a textiles retailer), the percentage of non-fixed carrier (water emissions)
	Pentadecafluorooctanoic Acid (PFOA)	335-67-1	1.01E-08	<0.01%	<0.01%	Concentration in PTFE (Amec Foster Wheeler, 2020)
	Copper - free metal impurity - not bound in the colourant	7440-50-8	4.74E-04	<0.01%	<0.01%	Data according to limit ETAD (2017) and depending on the amount of dye used.
Cotton	Nonyl phenol ethoxylates (NPEOs)	9016-45-9	8.57E-02	0.04%	0.01%	Direct data on product (Brigden et al., 2012) – blend cotton/PE taken as reference for whole product. The final amount is then shared among the materials depending on the manufacturing processes where NPEOs were used

352 Bao, Q., Fu, K., Ren, Q., Zhong, Y., Qian, D., Accuracy Profiles for Analyzing Residual Solvents in Textiles by GC-MS, Journal of Chromatographic Science, Volume 55, Issue 9, October 2017, Pages 882–890, https://doi.org/10.1093/chromsci/bmx052.

353 Note: according to ECHA, 2011, on final textile products "the residual DMAC evaporates during the processing of the fibres and the concentrations in the final fabric are below the detection limit". No ISO standard is available for DMAC. Gas chromatography and mass spectrometry (GC-MS) are required by OEKO-TEX 100 standard for solvents residues, https://www.oeko-tex.com/importedmedia/downloadfiles/OEKO-TEX_LEATHER_STANDARD_Testing_Methods_EN_DE.pdf.

354 Li X, Yang Y, Yang X, Li J, Li S, Tang S. Determination of Polycyclic Aromatic Hydrocarbons in Textiles by Gas Chromatography-Mass Spectrometry. AATCC Journal of Research. 2016;3(6):6-11. doi:10.14504/ajr.3.6.2.

355 ECHA Scientific report for evaluation of limit values for polycyclic aromatic hydrocarbons at the workplace Prepared by the European Chemicals Agency, 2022, https://echa.europa.eu/documents/10162/1b3bc755-ff8d-dd58-4b70-fc7329303b24.

Material	NIAS on the BC	CAS	Mass (g)	Concentration in material $C_{BC,material}$ (%)	Concentration in product $C_{BC,product}$ (%)	Set-up for calculation (i.e. mass balance/direct data on product) and sources
	White mineral oil	8042-47-5	6.56E-01	0.32%	0.13%	Based on direct data on product (Li et al., 2016) for naphthalene– coated denim fabric taken as reference for whole base case, and considering that naphthalene may be up to 1.5% of mineral oil (ECHA, 2022)
	Polycyclic aromatic hydrocarbons (PAH) e.g. naphthalene	91-20-3	4.77E-03	<0.01%	<0.01%	Direct data on product (Li et al., 2016) – coated denim fabric taken as reference for whole base case
	Pentadecafluorooctanoic Acid (PFOA)	335-67-1	8.56E-08	<0.01%	<0.01%	Concentration[356] in PTFE (Amec Foster Wheeler, [2020])
Nylon 6.6	Nonyl phenol ethoxylates (NPEOs)	9016-45-9	6.15E-04	0.01%	<0.01%	Direct data on product (Brigden et al., 2012) – blend cotton/PE taken as reference for whole product. The final amount is then shared among the materials depending on the manufacturing processes where NPEOs were used
	White mineral oil	8042-47-5	2.19E-02	0.32%	0.00%	Based on direct data on product (Li et al., 2016)[357] for naphthalene– coated denim fabric taken as reference for whole base case, and considering that naphthalene may be up to 1.5% of mineral oil (ECHA, 2022)[358]
	Polycyclic aromatic hydrocarbons (PAH) e.g. naphthalene	91-20-3	1.59E-04	<0.01%	<0.01%	Direct data on product (Li et al., 2016) – coated denim fabric taken as reference for whole base case
	Antimony trioxide	1309-64-4	1.62E-03	0.02%	<0.01%	Direct data on product (Brigden et al., 2014[359])
	Pentadecafluorooctanoic Acid (PFOA)	335-67-1	2.86E-09	<0.01%	<0.01%	Concentration in PTFE (Amec Foster Wheeler, [2020360])

356 Note: the concentration in the cited source was set according to the exemption as in Commission Delegated Regulation (EU) 2020/784 of 8 April 2020 amending Annex I to Regulation (EU) 2019/1021 of the European Parliament and of the Council as regards the listing of perfluorooctanoic acid (PFOA), its salts and PFOA-related compounds, OJ L 188I, 15.6.2020, p. 1–3.

357 Li X, Yang Y, Yang X, Li J, Li S, Tang S. Determination of Polycyclic Aromatic Hydrocarbons in Textiles by Gas Chromatography-Mass Spectrometry. AATCC Journal of Research. 2016;3(6):6-11. doi:10.14504/ajr.3.6.2.

358 ECHA Scientific report for evaluation of limit values for polycyclic aromatic hydrocarbons at the workplace Prepared by the European Chemicals Agency, 2022, https://echa.europa.eu/documents/10162/1b3bc755-ff8d-dd58-4b70-fc7329303b24.

359 Brigden, K., Santillo, D., Hetherington, M., Wang, S., Johnston, P., Greenpeace, Hazardous chemicals in branded luxury textile products on sale during 2013, Greenpeace Research Laboratories Technical Report 01/2012, https://www.greenpeace.to/greenpeace/wp-content/uploads/2014/02/Technical-Report-01-2014.pdf.

360 Amec Foster Wheeler Environment & Infrastructure GmbH (now part of Wood), The use of PFAS and fluorine-free alternatives in textiles, upholstry, carpets, leather and apparel, 2020, https://saicmknowledge.org/sites/default/files/resources/pfas_in_textiles_final_report_en.pdf.

Material	NIAS on the BC	CAS	Mass (g)	Concentration in material $c_{BC,material}$ (%)	Concentration in product $c_{BC,product}$ (%)	Set-up for calculation (i.e. mass balance/direct data on product) and sources
	Cyclic trimers of ethylene terephthalate	7441-32-9	2.08E-01	3%	0.04%	Direct data on the fibre (BREF for textiles)[361]
	Copper - free metal impurity - not bound in the colourant	7440-50-8	1.34E-04	<0.01%	<0.01%	Data according limit ETAD (2017) and depending on the amount of dye used.
Polyester fibres	Nonyl phenol ethoxylates (NPEOs)	9016-45-9	6.67E-03	0.01%	<0.01%	Direct data on product (Brigden et al., 2012) – blend cotton/PE taken as reference for whole product. The final amount is then shared among the materials depending on the manufacturing processes where NPEOs were used
	White mineral oil	8042-47-5	2.38E-01	0.32%	0.05%	Based on direct data on product (Li et al., 2016)[362] for naphthalene– coated denim fabric taken as reference for whole base case, and considering that naphthalene may be up to 1.5% of mineral oil (ECHA, 2022)[363]
	Polycyclic aromatic hydrocarbons (PAH) e.g. naphthalene	91-20-3	1.73E-03	<0.01%	<0.01%	Direct data on product (Li et al., 2016) – coated denim fabric taken as reference for whole Base Case
	1,2,4 - trichlorobenzene	120-82-1	2.57	3.42%	0.51%	Mass balance, considering mass of input carrier (BREF FOR TEXTILES)[364], water consumption (BREF FOR TEXTILES), number of uses of bath equal to 1 for batch dyeing (Information provided by a textiles retailer), the percentage of non-fixed carrier (water emissions)
	Pentadecafluorooctanoic Acid (PFOA)	335-67-1	3.10E-08	<0.01%	<0.01%	Concentration[365] in PTFE (Amec Foster Wheeler, 2020)
	Antimony trioxide	1309-64-4	1.76E-02	0.02%	<0.01%	Direct data on product (Brigden et al., 2014)

361 Note: it is supposed to remain on product after washings because it has a low solubility.

362 Li X, Yang Y, Yang X, Li J, Li S, Tang S. Determination of Polycyclic Aromatic Hydrocarbons in Textiles by Gas Chromatography-Mass Spectrometry. AATCC Journal of Research. 2016;3(6):6-11. doi:10.14504/ajr.3.6.2.

363 ECHA Scientific report for evaluation of limit values for polycyclic aromatic hydrocarbons at the workplace Prepared by the European Chemicals Agency, 2022, https://echa.europa.eu/documents/10162/1b3bc755-ff8d-dd58-4b70-fc7329303b24.

364 Note: according to BREF for textiles "Typical carrier formulations contain 60 – 80 % of active substance and 10 – 30 % of emulsifier and sometimes a small percentage of solvent". However, the data available in the BREF FOR TEXTILES are related to the active substance only (benzylbenzoate -based carriers, readily biodegradable substance, considered as a proxy, i.e. the same upper value of the range concentration is assumed for 1,2,4 – trichlorobenzene. The same value is confirmed also by Information provided by a textiles retailer data for chlorinated-based carriers).

365 Note: the concentration was set according to the exemption as in Commission Delegated Regulation (EU) 2020/784 of 8 April 2020 amending Annex I to Regulation (EU) 2019/1021 of the European Parliament and of the Council as regards the listing of perfluorooctanoic acid (PFOA), its salts and PFOA-related compounds, OJ L 188I, 15.6.2020, p. 1–3.

Material	NIAS on the BC	CAS	Mass (g)	Concentration in material $C_{BC,material}$ (%)	Concentration in product $C_{BC,product}$ (%)	Set-up for calculation (i.e. mass balance/direct data on product) and sources
	Cyclic trimers of ethylene terephthalate	7441-32-9	2.25	3%	0.45%	Direct data on the fibre (BREF for textiles) [366]
Recycled PET fibres	Nonyl phenol ethoxylates (NPEOs)	9016-45-9	1.23E-03	0.01%	<0.01%	Direct data on product (Brigden et al., 2012) – blend cotton/PE taken as reference for whole product. The final amount is then shared among the materials depending on the manufacturing processes where NPEOs were used
	White mineral oil	8042-47-5	4.38E-02	0.32%	0.01%	Based on direct data on product (Li et al., 2016)[367] for naphthalene– coated denim fabric taken as reference for whole base case, and considering that naphthalene may be up to 1.5% of mineral oil (ECHA, 2022)[368]
	Polycyclic aromatic hydrocarbons (PAH) e.g. naphthalene	91-20-3	3.19E-04	<0.01%	<0.01%	Direct data on product (Li et al., 2016) – coated denim fabric taken as reference for whole base case
	Benzaldehyde (*example for Volatile organic compounds (VOC)*)	100-52-7	2.11E-05	<0.01%	<0.01%	Direct data on product (Dutra et al., 2011) – PET R2 considered
	1,2,4 - trichlorobenzene	120-82-1	4.74E-01	3.42%	0.09%	Mass balance, considering mass of input carrier (BREF for textiles)[369], water consumption (BREF for textiles), number of uses of bath equal to 1 for batch dyeing (Information provided by a textiles retailer), the percentage of non-fixed carrier (water emissions)
	Pentadecafluorooctanoic Acid (PFOA)	335-67-1	5.71E-09	<0.01%	<0.01%	Concentration in PTFE (Amec Foster Wheeler, 2020[370])
	Antimony trioxide	1309-64-4	3.24E-03	0.02%	<0.01%	Direct data on product (Brigden et al., 2014)

366 Note: it is supposed to remain on product after washings because it has a low solubility.

367 Li X, Yang Y, Yang X, Li J, Li S, Tang S. Determination of Polycyclic Aromatic Hydrocarbons in Textiles by Gas Chromatography-Mass Spectrometry. AATCC Journal of Research. 2016;3(6):6-11. doi:10.14504/ajr.3.6.2.

368 ECHA Scientific report for evaluation of limit values for polycyclic aromatic hydrocarbons at the workplace Prepared by the European Chemicals Agency, 2022, https://echa.europa.eu/documents/10162/1b3bc755-ff8d-dd58-4b70-fc7329303b24.

369 Note: according to BREF FOR TEXTILES "Typical carrier formulations contain 60 – 80 % of active substance and 10 – 30 % of emulsifier and sometimes a small percentage of solvent". However, the data available in the BREF FOR TEXTILES are related to the active substance only (benzylbenzoate -based carriers, readily biodegradable substance, considered as a proxy, i.e. the same upper value of the range concentration is assumed for 1,2,4 – trichlorobenzene. The same value is confirmed also by Information provided by a textiles retailer data for chlorinated-based carriers).

370 Amec Foster Wheeler Environment & Infrastructure GmbH (now part of Wood), The use of PFAS and fluorine-free alternatives in textiles, upholstry, carpets, leather and apparel, 2020, https://saicmknowledge.org/sites/default/files/resources/pfas_in_textiles_final_report_en.pdf.

Material	NIAS on the BC	CAS	Mass (g)	Concentration in material $c_{BC,material}$ (%)	Concentration in product $c_{BC,product}$ (%)	Set-up for calculation (i.e. mass balance/direct data on product) and sources
	Cyclic trimers of ethylene terephthalate	7441-32-9	4.15E-01	3%	0.08%	Direct data on the fibre (BREF for textiles)
Viscose	Nonyl phenol ethoxylates (NPEOs)	9016-45-9	2.59E-03	0.03%	<0.01%	Direct data on product (Brigden et al., 2012) – blend cotton/PE taken as reference for whole product. The final amount is then shared among the materials depending on the manufacturing processes where NPEOs were used
	White mineral oil	8042-47-5	2.67E-02	0.32%	0.01%	Based on direct data on product (Li et al., 2016)[371] for naphthalene– coated denim fabric taken as reference for whole base case, and considering that naphthalene may be up to 1.5% of mineral oil (ECHA, 2022)[372]
	Polycyclic aromatic hydrocarbons (PAH) e.g. naphthalene	91-20-3	1.94E-04	<0.01%	<0.01%	Direct data on product (Li et al., 2016) – coated denim fabric taken as reference for whole base case
	Pentadecafluorooctanoic Acid (PFOA)	335-67-1	3.49E-09	<0.01%	<0.01%	Concentration[373] in PTFE (Amec Foster Wheeler, 2020)
Wool	Nonyl phenol ethoxylates (NPEOs)	9016-45-9	6.78E-02	0.05%	0.01%	Direct data on product (Brigden et al., 2012) – blend cotton/PE taken as reference for whole product. The final amount is then shared among the materials depending on the manufacturing processes where NPEOs were used
	White mineral oil	8042-47-5	4.63E-01	0.32%	0.09%	Based on direct data on product (Li et al., 2016) for naphthalene– coated denim fabric taken as reference for whole base case , and considering that naphthalene may be up to 1.5% of mineral oil (ECHA, 2022)
	Polycyclic aromatic hydrocarbons (PAH) e.g. naphthalene	91-20-3	3.37E-03	<0.01%	<0.01%	Direct data on product (Li et al., 2016) – coated denim fabric taken as reference for whole base case
	1,2,4 - trichlorobenzene	120-82-1	5.01	3.42%	1.00%	Mass balance, considering mass of input carrier (BREF FOR TEXTILES), water consumption (BREF FOR TEXTILES),

[371] Li X, Yang Y, Yang X, Li J, Li S, Tang S. Determination of Polycyclic Aromatic Hydrocarbons in Textiles by Gas Chromatography-Mass Spectrometry. AATCC Journal of Research. 2016;3(6):6-11. doi:10.14504/ajr.3.6.2.

[372] ECHA Scientific report for evaluation of limit values for polycyclic aromatic hydrocarbons at the workplace Prepared by the European Chemicals Agency, 2022, https://echa.europa.eu/documents/10162/1b3bc755-ff8d-dd58-4b70-fc7329303b24.

[373] Note: the concentration in the cited source was set according to the exemption as in Commission Delegated Regulation (EU) 2020/784 of 8 April 2020 amending Annex I to Regulation (EU) 2019/1021 of the European Parliament and of the Council as regards the listing of perfluorooctanoic acid (PFOA), its salts and PFOA-related compounds, OJ L 188I, 15.6.2020, p. 1–3.

Material	NIAS on the BC	CAS	Mass (g)	Concentration in material $c_{BC,material}$ (%)	Concentration in product $c_{BC,product}$ (%)	Set-up for calculation (i.e. mass balance/direct data on product) and sources
						number of uses of bath equal to 1 for batch dyeing (Information provided by a textiles retailer), the percentage of non-fixed carrier (water emissions)
	Pentadecafluorooctanoic Acid (PFOA)	335-67-1	6.04E-08	<0.01%	<0.01%	Concentration in PTFE (Amec Foster Wheeler, 2020[374])
	Copper - free metal impurity - not bound in the colourant	7440-50-8	2.84E-03	<0.01%	<0.01%	Data according limit ETAD (2017) in the dye and depending on the amount of dye used.

Source: JRC's own elaboration.

Table 29. Input amounts and emissions during manufacturing[375] of the Base Case (a_{LC}) (functional substances and auxiliary substances, i.e. process chemicals, not designed to remain in the product). The processes listed in this table correspond to the processes reported in **Figure 13**.

Substances	CAS	Type	Process	Material	Input (g) a_{LC}	Air emission (g) a_{LC}	Freshwater emission (g) a_{LC}	Soil emission (g) a_{LC}	Set-up for calculation (i.e. mass balance/direct data on emission) and sources
N,N - Dimethylacetamide	127-19-5	Auxiliary (solvent)	Fibres manufacturing	acrylic	1.41E+01	1.30E+01	7.26E-02	-	Mass balance between input in acrylic fibres production (ECHA, 2012)[376], content on fibres (BREF for textiles page 385) and water emissions (BREF for textiles)
			Drying	acrylic	-	1.09E+00	-	-	Mass balance with residual content on fibres
Carbon disulphide	75-15-0	Auxiliary (solvent)	Fibres manufacturing	viscose	1.61E+00	5.31E-01	-	-	Air emissions from BREF on polymers[377] for staple fibres (Table 11.1)
			Scouring	viscose	-	-	9.38E-01	-	Mass balance with residual content on fibres, determined considering input in viscose production, water emissions of COD and AOX and air emissions of sulphur (BREF on polymers)

374 Amec Foster Wheeler Environment & Infrastructure GmbH (now part of Wood), The use of PFAS and fluorine-free alternatives in textiles, upholstry, carpets, leather and apparel, 2020, https://saicmknowledge.org/sites/default/files/resources/pfas_in_textiles_final_report_en.pdf.

375 Note: depending on the position of the processes in the manufacturing sequences, the emissions may be referred to amounts of materials that are different from one process to another (considering materials losses). However, these emissions are due to the manufacturing of a final product assumed weighing 0.5 kg.

376 European Chemical Agency (ECHA), Draft background document for N,N-Dimethylacetamide (DMAC), 2012, https://echa.europa.eu/documents/10162/75273ecf-4846-42cd-affa-420d425c1e6f.

377 European Commission, 2007, BAT (Best Available Techniques) Reference Document (BREF) entitled "Best Available Techniques for the Production of Polymers" (POL).

Substances	CAS	Type	Process	Material	Input (g) a_{LC}	Air emission (g) a_{LC}	Freshwater emission (g) a_{LC}	Soil emission (g) a_{LC}	Set-up for calculation (i.e. mass balance/direct data on emission) and sources
Zinc sulphate	7733-02-0	Auxiliary (solvent)	Fibres manufacturing	viscose	9.74E-01	-	9.74E-01	-	Mass balance between input in viscose production (Guo et al (2021)) and residues remained on fibres (presence according to BREF for textiles, concentration according to limit of detection (LOD) of Zn (Rujido-Santos et al., 2022)[378]
			Scouring	viscose	-	-	6.03E-06	-	Mass balance with residual content on fibres
AOX, Adsorbable Organic Halogen[379]	-	Degradation product	Fibres manufacturing	viscose	-	-	3.54E-04	-	Water emissions from BREF on polymers for staple fibres (Table 11.1)
COD (Chemical Oxygen Demand)	-	Degradation product	Fibres manufacturing	viscose	-	-	1.42E-01	-	Water emissions from BREF on polymers for staple fibres (Table 11.1)
Sulfuric acid	7664-93-9	Auxiliary	Fibres manufacturing	viscose	1.82E+01	5.31E-01 (as sulphur)	8.76E+00 (as sulphate ion, due also to the contribution of carbon disulfide)	-	Input amount and emissions from BREF on polymers (Table 11.1)
Antimony trioxide	1309-64-4	Functional chemical that from the matrix arises to the surface of fibres during dyeing (becoming a NIAS)	Fibre manufacturing	PES, PET-recycled, nylon 6.6	5.49E-02	-	7.91E-03	-	Input amount calculated based on own elaboration from Ecoinvent 3.9.1 (Wernet et al., 2016)[380] (referred to antimony only and assumed as proxy for antimony trioxide). Emission calculated with mass balance considering amount on fibres (Brigden et al., 2014)

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378 Rujido-Santos, I.; Herbello-Hermelo, P.; Barciela-Alonso, M.C.; Bermejo-Barrera, P.; Moreda-Piñeiro, A. Metal Content in Textile and (Nano)Textile Products. Int. J. Environ. Res. Public Health 2022, 19, 944. https://doi.org/10.3390/ ijerph19020944.

379 “AOX” and “COD” do not represent specific substances, but parameters monitored for water quality assessment. They are listed here as relevant emission.

380 Wernet, G., Bauer, C., Steubing, B., Reinhard, J., Moreno-Ruiz, E., and Weidema, B., 2016. The ecoinvent database version 3 (part I): overview and methodology. The International Journal of Life Cycle Assessment, [online] 21(9), pp.1218–1230. Available at: http://link.springer.com/10.1007/s11367-016-1087-8.

Substances	CAS	Type	Process	Material	Input (g) a_{LC}	Air emission (g) a_{LC}	Freshwater emission (g) a_{LC}	Soil emission (g) a_{LC}	Set-up for calculation (i.e. mass balance/direct data on emission) and sources
Diazinon	333-41-5	Auxiliary (pesticide)	Raw wool and cashmere production (agricultural phase)	Raw wool and cashmere	8.05E-02	-	-	7.73E-02	Mass balance between input (Ward and Armstrong, 2001)[381] and content on fibres (BREF for textiles page 30)
			Scouring	wool and cashmere	-	-	3.22E-03	-	Mass balance with residual content on fibres
Chlorpyrifos	2921-88-2	Auxiliary (pesticide)	Raw cotton production (agricultural phase)	cotton	3.26E-03	-	-	3.13E-03	Mass balance between input (determined assuming the same proportionality for wool residues from BREF) and content on fibres (Attallah et al., 2017)[382]
			Scouring	cotton	-	-	-	1.30E-04	Mass balance with residual content on fibres
Nonyl phenol ethoxylates (NPEOs)	9016-45-9	Auxiliary (surfactant)	Scouring	viscose, wool, cotton and cashmere	1.28E+01	-	1.32E+01	-	Due to detergent used in scouring and the emulsifier used in preparation agents for spinning in fibres (in fibres manufacturing) of viscose, wool, cotton and cashmere. Mass balance between input (BREF for textiles page 416)[383] and content on product (Brigden et al., 2012[384]). For input amount of preparation agent in spinning in fibres, values from Guo et al., 2021[385] are considered.
			Washing	all	2.10E+01	-	2.09E+01	-	Due to emulsifier in preparation agent for spinning in yarn (i.e. dry spinning) and detergent used in washing. Mass balance between input (BREF for textiles Table 8.4) and content on product (Brigden et al., 2012)
			Bleaching	viscose, wool, cotton	5.46E+00	-	5.42E+00	-	Emissions deriving from discharge of input amount from BREF for textiles table 8.32 for cotton and page 924 for wool

381 Ward, M. and Armstrong, R. (2001), Surveys to assess the amount of pesticide in wool and the use of pesticides by woolgrowers in Queensland. Australian Veterinary Journal, 79: 358-362. https://doi.org/10.1111/j.1751-0813.2001.tb12014.x.

382 Attallah, E.R and Abdelwahed, M. H., 'Monitoring of Pesticide Residues in some Cotton Products in Egypt using GCMS/MS and LC-MS/MS', Middle East J. Appl. Sci., 2017, 7(1), p. 102-109, 2017.

383 Note: detergent assumed made of NPEOs only. Table 8.8 BREF FOR TEXTILES does not report additional function of chemicals for detergents.

384 Brigden, K., Santillo, D., Johnston, P., Greenpeace, Nonylphenol ethoxylates (NPEs) in textile products, and their release through laundering, Greenpeace Research Laboratories Technical Report 01/2012, https://www.greenpeace.org/static/planet4-international-stateless/2012/03/806ceff8-dirty_laundry_product_testing_technical_report_01-2012.pdf.

385 Guo, S., Li, X., Zhao, R. et al. Comparison of life cycle assessment between lyocell fiber and viscose fiber in China. Int J Life Cycle Assess 26, 1545–1555 (2021). https://doi.org/10.1007/s11367-021-01916-y.

Substances	CAS	Type	Process	Material	Input (g) a_{LC}	Air emission (g) a_{LC}	Freshwater emission (g) a_{LC}	Soil emission (g) a_{LC}	Set-up for calculation (i.e. mass balance/direct data on emission) and sources
				and cashmere					(considering water consumption for bleaching based on table 4.59) and content on product (Brigden et al., 2012)
			Dyeing	cotton, viscose	4.10E+00	-	4.08E+00	-	Mass balance between input (Table 4.8 BREF for textiles) and residual content on fibres (calculated considering Bridget et al., 2012)
			Dyeing	PES, r-PET, acrylic	2.10E+00	-	2.10E+00	-	Emissions deriving from discharge of input (BREF for textiles Table 4.81 – referred to standard disperse dyeing), assumed to not be retained by synthetic fibres
			Finishing (anti felt)	wool and cashmere	8.54E-01	-	8.32E-01	-	Mass balance between input (BREF for textiles Table 8.45, about the pre-treatment for printing of wool with chlorine-containing substances, assumed as proxy for finishing, since it has a very similar recipe) and residual content on fibres (calculated considering Bridget et al., 2012)
White mineral oil	8042-47-5	Auxiliary (lubricant)	Scouring	viscose, wool, cotton and cashmere	-	-	1.60E+00	-	Due to the mineral oil used in preparation agents for spinning in fibres (in fibres manufacturing) of viscose, wool, cotton and cashmere.
			Spinning (in fibres manufacturing and as dry spinning)	all	5.19E+01	-	-	-	For input amount of preparation agent in spinning in fibres (in fibres manufacturing), values from Guo et al., 2021 are considered. For input amount for spinning in yarn (i.e. dry spinning), values from BREF for textiles (Table 8.4) are considered
			Knitting	all	8.38E+01	-	-	9.27E-01	Soil emission of waste oil elaborated from Ecoinvent 3.9.1 (Wernet et al., 2016)[386].
			Washing	all	-	-	1.30E+02	-	Due to mineral oil in preparation agent for spinning and to mineral oil for knitting. Mass balance with input, depending on the amount of mineral oil and naphthalene remaining on product (Li et al., 2016)
Naphthalene	91-20-3	Impurity (from white mineral oil)	Scouring	viscose, wool, cotton and	-	-	2.43E-02	-	Due to the mineral oil used in preparation agents for spinning in fibres of viscose, wool, cotton and cashmere. For input amount of preparation agent in spinning in fibres, values from Guo et al., 2021 are considered

386 Wernet, G., Bauer, C., Steubing, B., Reinhard, J., Moreno-Ruiz, E., and Weidema, B., 2016. The ecoinvent database version 3 (part I): overview and methodology. The International Journal of Life Cycle Assessment, [online] 21(9), pp.1218–1230. Available at: http://link.springer.com/10.1007/s11367-016-1087-8.

Substances	CAS	Type	Process	Material	Input (g) a_{LC}	Air emission (g) a_{LC}	Freshwater emission (g) a_{LC}	Soil emission (g) a_{LC}	Set-up for calculation (i.e. mass balance/direct data on emission) and sources
				cashmere					
			Knitting	all	-	-	-	1.39E-02	Soil emission of waste oil elaborated from Ecoinvent 3.9.1 (Wernet et al., 2016)[387], depending on the amount of mineral oil
			Washing	all	-	-	1.99E+00	-	Due to naphthalene in mineral oil of preparation agent for spinning and in mineral oil for knitting. Mass balance with input, depending on the amount of mineral oil and naphthalene remaining on product (Li et al., 2016)
Imidazole	288-32-4	Auxiliary (biocide in spinning)	Washing	all	2.10E-03	-	2.10E-03	-	Mass balance considering that total input (BREF for textiles data page 845) is emitted in subsequent washing
Sodium hypochlorite	7681-52-9	Auxiliary (bleaching agent)	Bleaching	cotton	1.30E+01	-	1.30E+01	-	Emissions deriving from discharge of input amount from BREF for textiles Table 8.32
		Functional chemical (anti-felt treatment)	Finishing	wool and cashmere	1.03E+01	-	2.56E+00	-	Mass balance, input chemicals (BREF for textiles Table 8.45) and fraction that remains on fibres (Information provided by a textiles retailer)
Hydrogen peroxide	7722-84-1	Auxiliary (bleaching agent)	Bleaching	wool and cashmere	2.68E+01	-	2.68E+01	-	Emissions deriving from discharge of input amount from BREF for textiles Table 8.43
Ethylenediaminetetraacetic acid (EDTA)	60-00-4	Auxiliary (sequestering agent)	Washing	all	1.05E+01	-	1.05E+01	-	Emissions deriving from discharge of input amount from BREF for textiles Table 8.37
			Bleaching	wool and cashmere	2.38E+01	-	2.38E+01	-	Emissions deriving from discharge of input amount from BREF for textiles Table 8.43
Sodium hydroxide	1310-73-2	Auxiliary (alkaline)	Bleaching	cotton	6.52E+00	-	6.52E+00	-	Emissions deriving from discharge of input amount from BREF for textiles Table 8.32
Disperse Blue 35	12222-75-2	Functional chemical (dye)	Dyeing	PES, recycled PET, acrylic	5.85E+00	-	5.85E-02	-	Emission calculated considering mass of input generic standard disperse dye (Table 4.81 BREF for textiles), number of uses of bath equal to 1 for batch dyeing (Information provided by a textiles retailer), and the percentage of non-fixed dye

[387] Wernet, G., Bauer, C., Steubing, B., Reinhard, J., Moreno-Ruiz, E., and Weidema, B., 2016. The ecoinvent database version 3 (part I): overview and methodology. The International Journal of Life Cycle Assessment, [online] 21(9), pp.1218–1230. Available at: http://link.springer.com/10.1007/s11367-016-1087-8.

Substances	CAS	Type	Process	Material	Input (g) a_{LC}	Air emission (g) a_{LC}	Freshwater emission (g) a_{LC}	Soil emission (g) a_{LC}	Set-up for calculation (i.e. mass balance/direct data on emission) and sources
									discharged (Table 2.16 BREF for textiles, Euratex data) (generally referred to disperse dyes)
Reactive Blue 72	61968-93-2	Functional chemical (dye)	Dyeing	wool, cashmere, nylon 6.6	1.42E+01	-	4.27E-01	-	Emission calculated considering mass of input dye (BREF for textiles Table 4.71), number of reuses of bath (BREF for textiles) and the percentage of non-fixed dye discharged (Table 2.16 BREF for textiles, Euratex data) (generally referred to reactive dyes)
Copper	7440-50-8	Impurity in Reactive Blue 72	Reactive dyeing	wool, cashmere, nylon 6.6	-	-	1.07E-04	-	Data according limit ETAD (2017) in the dye and depending on the amount of dye used.
Direct Orange 62	12222-38-7	Functional chemical (dye)	Dyeing	cotton, viscose	1.30E+01	-	5.18E-01	-	Emission calculated considering mass of input dye (Information provided by a textiles retailer), number of uses of bath equal to 1 for batch dyeing (Information provided by a textiles retailer) and the percentage of non-fixed dye discharged (Table 8.12 BREF for textiles, Euratex data)
Sodium chloride	7647-14-5	Auxiliary (salt)	Dyeing	all	2.42E+02	-	2.42E+02	-	BREF Table 2.19 about reactive and direct dyeing. Disperse dyeing assumed to direct dyeing. The same amount is then supposed to be emitted for mass balance.
Acetic acid	64-19-7	Auxiliary (pH adjuster)	Dyeing	PES, recycled PET, wool, cashmere, nylon 6.6	7.10E+00	-	7.10E+00	-	Mass balance with input in dyeing (Table 4.81 BREF for textiles), number of uses of bath equal to 1 for batch dyeing (Information provided by a textiles retailer). The same amount is then supposed to be emitted since the substance is not designed to remain on the product.
			Finishing	wool, cashmere	5.13E+00	-	5.13E+00	-	Emission due to discharge of input for finishing (BREF for textiles Table 8.45, about the pre-treatment for printing of wool with chlorine-containing substances, assumed as proxy for finishing, since it has a very similar recipe)
Polyvinylpyrrolidone	9003-39-8	Auxiliary (levelling agent)	Dyeing	cotton and viscose	4.10E+00	-	4.10E+00	-	Emissions deriving from discharge of input amount since the substance is not designed to remain on the product. Input amount calculated considering data about concentration in water (Information provided by a textiles retailer, with max value assumed for conservative purposes), complemented with data about water consumption (9.5 l water/kg for dyeing bath, excluded rinsing) reported in BREF for textiles (assuming liquor ratio 1:10 as reported by Information provided by a textiles retailer), number of uses of bath equal to 1 for batch dyeing (Information provided by a textiles retailer), and assuming the same water consumption for all fibres types.

Substances	CAS	Type	Process	Material	Input (g) a_{LC}	Air emission (g) a_{LC}	Freshwater emission (g) a_{LC}	Soil emission (g) a_{LC}	Set-up for calculation (i.e. mass balance/direct data on emission) and sources
Sodium dithionite	7775-14-6	Auxiliary (reductor)	Bleaching	wool and cashmere	6.71E+00	-	6.71E+00	-	Emissions deriving from discharge of input amount from BREF for textiles page 924 for wool (considering water consumption for bleaching based on table 4.59)
Ammonia	7664-41-7	Auxiliary (after-treatment for dye high fastness)	Dyeing	wool, cashmere, nylon 6.6	4.44E-01	-	4.44E-01	-	Mass balance with input in dyeing (Table 8.42 BREF for textiles-assumed as washing after dyeing), number of uses of bath equal to 1 for batch dyeing (Information provided by a textiles retailer). The same amount is then assumed to be emitted since the chemical is not designed to remain on the product.
Formaldehyde condensation products with amines	94645-56-4	Auxiliary (after treatment/fixer)	Dyeing	cotton and viscose	8.64E+00	-	6.91E+00	-	Mass balance with input in dyeing (Information provided by a textiles retailer) and amount remaining on fibres (Information provided by a textiles retailer)
Lauryl amine ethoxylated	31017-83-1	Auxiliary (levelling agent)	Dyeing	PES, recycled PET, acrylic, wool, cashmere, nylon 6.6	5.40E+00	-	5.40E+00	-	Emissions deriving from discharge of input amount since the substance is not designed to remain on the product. Input amount calculated considering data about concentration in water (Information provided by a textiles retailer, with max value assumed for conservative purposes), complemented with data about water consumption (9.5 l water/kg for dyeing bath, excluded rinsing) reported in BREF for textiles (assuming liquor ratio 1:10 as reported by Information provided by a textiles retailer), number of uses of bath equal to 1 for batch dyeing (Information provided by a textiles retailer), and assuming the same water consumption for all fibres types.
Sodium carbonate	497-19-8	Auxiliary (alkaline)	Dyeing	cotton, viscose	2.08E+02	-	2.08E+02	-	Emissions deriving from discharge of input amount since the substance is not designed to remain on the product. Input amount calculated considering data about concentration in water (Information provided by a textiles retailer, with max value assumed for conservative purposes), complemented with data about water consumption (9.5 l water/kg for dyeing bath, excluded rinsing) reported in BREF for textiles (assuming liquor ratio 1:10 as reported by Information provided by a textiles retailer), number of uses of bath equal to 1 for batch dyeing (Information provided by a textiles retailer), and assuming the same water consumption for all fibres types.
1,2,4, trichlorobenzene	120-82-1	Auxiliary (carrier)	Dyeing	PES, recycled PET	4.04E+00	-	4.04E-01	-	Mass balance, considering mass of input (BREF for textiles page 700), number of uses of bath equal to 1 for batch dyeing

Substances	CAS	Type	Process	Material	Input (g) a_{LC}	Air emission (g) a_{LC}	Freshwater emission (g) a_{LC}	Soil emission (g) a_{LC}	Set-up for calculation (i.e. mass balance/direct data on emission) and sources
									(Information provided by a textiles retailer), and the percentage of non-fixed carrier discharged
Hexa(methoxymethyl)melamine	3089-11-0	Functional chemical (cross-linking agent)	Finishing	cotton and viscose	6.48E+01	1.39E-01 (as Formaldehyde, CAS 50-00-0) 4.15E-01 (as Methanol, CAS 67-56-1)	4.48E+01	-	Air emissions from BREF for textiles Table 4.86 Water emissions with mass balance, considering mass of input for finishing with no crease agent (Information provided by a textiles retailer), the air emissions of methanol and formaldehyde (Table 4.86 BREF for textiles) and amount on fibres (Information provided by a textiles retailer)
Polysiloxane	161755-53-9	Functional chemical (softner)	Finishing	cotton and viscose	1.08E+01	-	8.85E+00	-	Mass balance, considering mass of input for finishing with no crease agent (Information provided by a textiles retailer) and amount on fibres (Information provided by a textiles retailer)
Ammonium sulfate	7783-20-2	Auxiliary (catalyst)	Finishing	cotton and viscose	3.24E+00	3.24E+00		-	Emission due to discharge of input for finishing with no crease agent (Information provided by a textiles retailer). No information available about the persistency of chemical on the fibres, so it is assumed to be emitted.
Polytetrafluoroethylene (PTFE)	9002-84-0	Functional chemical (water repellent)	Finishing	all	5.84E+01	-	5.02E+01	-	Mass balance, considering mass of input for finishing with water repellent and water consumption (Table 4.89 BREF on textiles for padding process with PFC-C8-based agent, formulation assumed from SDS[388] [389]), PFOA content and PFOA emissions and amount of water repellent on fibres (the latter as Information provided by a textiles retailer).
Pentadecafluorooctanoic Acid (PFOA)	335-67-1	Impurity (PTFE)	Finishing	all	-	-	1.25E-06	-	Mass balance, PFOA content in PTFE (Amec Foster Wheeler, 2020[390])

388 https://www.quintech.de/wp-content/uploads/2020/07/SDS-TeflonDISP30-2018-ENG.pdf. The source is consulted only for the purpose of obtaining information about the composition of the mixture. It is not intended as a proof of compliance with Annex II of REACH.

389 https://inolub.com/pdf/Inolub%20WD%20SDS_Eng.pdf. The source is consulted only for the purpose of obtaining information about the composition of the mixture. It is not intended as a proof of compliance with Annex II of REACH.

390 Amec Foster Wheeler Environment & Infrastructure GmbH (now part of Wood), The use of PFAS and fluorine-free alternatives in textiles, upholstry, carpets, leather and apparel, 2020, https://saicmknowledge.org/sites/default/files/resources/pfas_in_textiles_final_report_en.pdf.

Substances	CAS	Type	Process	Material	Input (g) a_{LC}	Air emission (g) a_{LC}	Freshwater emission (g) a_{LC}	Soil emission (g) a_{LC}	Set-up for calculation (i.e. mass balance/direct data on emission) and sources
Sodium bisulphite	7631-90-5	Auxiliary (anti-chlorine treatment)	Finishing	wool, cashmere	6.83E+00	-	6.83E+00	-	Emission due to discharge of input for finishing (BREF for textiles Table 8.45, about the pre-treatment for printing of wool with chlorine-containing substances, assumed as proxy for finishing, since it has a very similar recipe)
Polymer (PA) based resin with epichlorohydrin	(proxy with 106-89-8 epichlorohydrin)	Functional chemical (anti-felt treatment)	Finishing	wool, cashmere	5.13E+00	-	1.28E+00	-	Mass balance, input chemicals (BREF for textiles Table 8.45, about the pre-treatment for printing of wool with chlorine-containing substances, assumed as proxy for finishing, since it has a very similar recipe) and fraction that remains on fibres (Information provided by a textiles retailer)
2,6,8-Trimethyl-4-nonyloxypolyethyleneoxyethanol	60828-78-6	Functional chemical (water repellent)	Finishing	all	3.19E+00	-	2.74E+00	-	Mass balance, considering mass of input for finishing with water repellent and water consumption (Table 4.89 BREF on textiles for padding process with PFC-C8-based agent, formulation assumed from SDS[391] [392]), PFOA content in PTFE and PFOA emissions and amount of water repellent on fibres (the latter as Information provided by a textiles retailer).

Source: JRC's own elaboration.

Table 30. Emissions from the Base Case during the use stage (domestic washings) (a_{LC}).

Substances	Type	CAS	Freshwater emission (g)	Set-up for calculation (i.e. mass balance/direct data on emission) and sources
Disperse Blue 35	Functional chemical	12222-75-2	5.79	Mass balance, direct data on recycled materials from RI.SE, 2019[393] (proxy with post-consumer waste)
Hexa(methoxymethyl)melamine	Functional chemical	3089-11-0	1.94E+01	Calculated considering data about emissions of formaldehyde after one washing cycle from Piccinini et al., 2007[394] (considering the 17 washings in the Case Study the amount would be all emitted)

[391] https://www.quintech.de/wp-content/uploads/2020/07/SDS-TeflonDISP30-2018-ENG.pdf. The source is consulted only for the purpose of obtaining information about the composition of the mixture. It is not intended as a proof of compliance with Annex II of REACH.

[392] https://inolub.com/pdf/Inolub%20WD%20SDS_Eng.pdf. The source is consulted only for the purpose of obtaining information about the composition of the mixture. It is not intended as a proof of compliance with Annex II of REACH.

[393] Research Institute of Sweden (RI.SE), REPORT Results of analyses for Classification and risk assessment of textiles for material recycling – Funded by Vinnova 2017- 2019, https://www.ri.se/sites/default/files/2020-11/Classification%20and%20risk%20assessment_analytical%20results.pdf

[394] Piccinini, P., Senaldi, C., Summa, C., Joint Research Centre, European survey on the release of formaldehyde from textiles, 2007, https://op.europa.eu/en/publication-detail/-/publication/0c78639b-c5bd-4fb9-af32-ae559a58078d#:~:text=A%20European%20survey%20on%20the%20level%20of%20formaldehyde,of%20fibres%20and%20type%20of%20garments%20as%20possible.

Substances	Type	CAS	Freshwater emission (g)	Set-up for calculation (i.e. mass balance/direct data on emission) and sources
Formaldehyde condensation products with amines	Functional chemical	94645-56-4	1.73	Calculated considering data about decrease in concentration (10%) of formaldehyde after one washing cycle from Piccinini et al., 2007 (with the 17 washings in the Case Study the amount would be all emitted)
Polysiloxane	Functional chemical	161755-53-9	1.94	Since the chemical is reported as temporal by Information provided by a textiles retailer, the amount present of the fabric is assumed to be entirely washed during use stage
Polytetrafluoroethylene (PTFE)	Functional chemical	9002-84-0	5.97	Reduction of PFOA on sample FC-8 PES before and after ageing, 10 washings and tumble dryings (van der Veen et al., 2022)[395]. Assumed the same reduction for PTFE, allocated to the fraction of PTFE in the mixture of the water repellent agent.
2,6,8-Trimethyl-4-Nonyloxypolyethyleneoxyethanol	Functional chemical	60828-78-6	3.25E-01	Assumed the same reduction for PFOA, depending on the presence of 2,6,8-Trimethyl-4-Nonyloxypolyethyleneoxyethanol in the mixture of the water repellent agent.
(benzothiazol-2-ylthio)methyl thiocyanate; TCMTB	Functional chemical	21564-17-0	1.35E-02	Emission of benzothiazole derivative calculated considering the decrease in concentration after ten washings (53 %) (Luongo et al., 2016)[396]
Reactive Blue 72	Functional chemical	61968-93-2	3E-01	Data about reactive dye discharge (Zhao et al., 2022)
Sodium hypochlorite*	Functional chemical	7681-52-9	7.69	Calculated considering information about gradual release of dichloroisocyanuric acid (DCCA) (assumed as proxy since it has the same function) during washings from Kettlewell et al., 2015[397]
Polymer (PA) based resin with epichlorohydrin*	Functional chemical	proxy with 106-89-8 epichlorohydrin	3.84	proxy with dichloroisocyanuric acid (DCCA) (complementary function) from Kettlewell et al., 2015
Direct Orange 62	Functional chemical	12222-38-7	3.01E-01	Data about reactive dye discharge – proxy for direct dyes (Zhao et al., 2022)
Titanium dioxide	Functional chemical	13463-67-7	0	*Since it is in the matrix, it is assumed not to be washed away*
Decabromodiphenyl ethane (DBDPE)	Functional chemical	84852-53-9	0	*Since it is in the matrix, it is assumed not to be washed away*
Nonyl phenol ethoxylates (NPEOs)*	NIAS	9016-45-9	1.78E-01	Calculated considering data about emissions from Brigden et al., 2012 and the number of washes for the Base Case (the entire amount on the Base Case would be emitted)
Pentadecafluorooctanoic Acid (PFOA)	NIAS	335-67-1	1.49E-07	Reduction of PFOA on sample FC-8 PES before and after ageing, 10 washings and tumble dryings (van der Veen et al., 2022)

395 van der Veen, I., Schellenberger, St., Hanning, A. C., Stare, A., de Boer, J., Weiss, J. M., Leonards, P. E. G., Fate of Per- and Polyfluoroalkyl Substances from Durable Water-Repellent Clothing during Use, Environmental Science & Technology, 2022, M3 - doi: 10.1021/acs.est.1c07876.

396 Luongo, G., Avagyan, R., Hongyu, R. et al. The washout effect during laundry on benzothiazole, benzotriazole, quinoline, and their derivatives in clothing textiles. Environ Sci Pollut Res 23, 2537–2548 (2016). https://doi.org/10.1007/s11356-015-5405-7.

397 R. Kettlewell , A. De Boos , J. Jackson, Commercial shrink-resist, finishes for wool, 2015, Australian Wool Innovation Limited , Sydney, NSW, Australia, chapter in Functional Finishes for Textiles Improving Comfort, Performance and Protection, A volume in Woodhead Publishing Series in Textiles, https://www.sciencedirect.com/book/9780857098399/functional-finishes-for-textiles?via=ihub=.

Substances	Type	CAS	Freshwater emission (g)	Set-up for calculation (i.e. mass balance/direct data on emission) and sources
Copper	NIAS	7440-50-8	0	*No specific data were found, thus NIAS in the product are assumed not washed away during the use stage*
Naphthalene	NIAS	91-20-3	0	*No specific data were found, thus NIAS in the product are assumed not washed away during the use stage*
White mineral oil	NIAS	8042-47-5	0	*No specific data were found, thus NIAS in the product are assumed not washed away during the use stage*
Benzaldehyde	NIAS	100-52-7	0	*No specific data were found, thus NIAS in the product are assumed not washed away during the use stage*
1,2,4 - trichlorobenzene	NIAS	120-82-1	0	*No specific data were found, thus NIAS in the product are assumed not washed away during the use stage*
Antimony trioxide	NIAS	1309-64-4	0	*No specific data were found, thus NIAS in the product are assumed not washed away during the use stage*
Cyclic trimers of ethylene terephthalate	NIAS	7441-32-9	0	*No specific data were found, thus NIAS in the product are assumed not washed away during the use stage*
Micro-fibres	NIAS	-	2.62	Data about emission from wool – proxy for whole product (Anselmi et al., 2023)[398]

Source: JRC's own elaboration.

Note: according to inventory results, substances marked with asterisk "*" are entirely emitted during use phase and will not be found on post-consumer waste.

[398] Anselmi, S.; Provenza, F.; Bentivoglio, T.; Picerno, G.; Cavallo, A.; Renzi, M. Marine Biodegradability and Ecotoxicity of MWool® Recycled Wool Fibers: A Circular-Economy-Based Material. Oceans 2023, 4, 114-131. https://doi.org/10.3390/oceans4010009.

With regard to **Table 27. List of possible non-intentionally added substances to the Base Case**, the presence on NPEOs and PAH was detected also in the analytical tests on mechanically recycled post-consumer waste, as described in RI.SE, 2019[399]. It is to be noticed that NPEOs are restricted in detergents for industrial and domestic washing in the EU under REACH, and mechanical recycling should not introduce new chemicals into the material. Thus it can be assumed that the use stage did not play a role in contaminating the product in Sweden.

According to the report, performing the analysis with mechanical recycling will provide the worst-case scenario, since the chemical content should not change. However, the sample preparation should be taken into account. The materials selected for analyses were sorted by separating specific fibre types and use of the textile. The garments were then washed in an industrial washing machine at 40 or 60 degrees Celsius and dried in a tumble dryer at maximum 50 degrees Celsius. Given the procedure followed for the preparation, we can assume that the waste collection and sorting was performed in Sweden and no contamination occurred with worldwide collected textile waste.

Thus, the misalignment about NPEOs presence in the post-consumer waste between the mentioned source and the results of this study in **Table 27** is due to the data modelling for the inventory, where NPEOs resulted to be all emitted during domestic washing. Indeed, this was calculated applying a mass balance to the original content of NPEOs and their leaching resulting from the number of washings for the lifespan (5 uses before washing, 85 uses for the Base Case) and the percentage discharge after first washing according to the Greenpeace report (Brigden et al., 2012[400]). Thus, even if not accounted for with the reported procedure, NPEOs are flagged by this source to be potentially present in post-consumer waste and in recycled materials.

Regarding freshwater emissions of Disperse Blue 35 during the use stage, as specified in **Table 30** the data on mechanically-recycled post-consumer waste textiles are considered as a proxy for post-consumer waste. Mechanical recycling does not affect the chemical composition itself; however, in the RI.SE report, a pre-treatment consisting in washing and drying is mentioned, which could actually lower the dye concentration in the textile material.

In **Table 31** additional emissions related to degradation compounds are reported. The BREF for textiles reports emission factors of organic carbon as a function of the temperature and duration of the test. Below the main emissions of degraded compounds are flagged and suggested for further possible analysis, if possible,in the Preparatory Study.

Table 31. Non exhaustive list of the identified degradation compounds emitted during manufacturing – not quantified in the inventory.

Original compound (CAS number)	Process of emission	Degradation compound	Emission compartment	Sources
White mineral oil (8042-47-5)	Heat setting and drying	Volatile organic compounds (VOCs)	Air (also indoor)	BREF for textiles page 372

399 Research Institute of Sweden (RI.SE), REPORT Results of analyses for Classification and risk assessment of textiles for material recycling – Funded by Vinnova 2017- 2019, https://www.ri.se/sites/default/files/2020-11/Classification%20and%20risk%20assessment_analytical%20results.pdf.

400 Brigden, K., Santillo, D., Johnston, P., Greenpeace, Nonylphenol ethoxylates (NPEs) in textile products, and their release through laundering, Greenpeace Research Laboratories Technical Report 01/2012, https://www.greenpeace.org/static/planet4-international-stateless/2012/03/806ceff8-dirty_laundry_product_testing_technical_report_01-2012.pdf.

Original compound (CAS number)	Process of emission	Degradation compound	Emission compartment	Sources
Hydrogen peroxide (7722-84-1)	Bleaching	Adsorbable organically bound halogens (AOX) - If mixed with effluents containing inorganic chlorides (e.g. NaCl from dyeing) e.g. trichloromethane (67-66-3); chloroacetic acid (79-11-8)	Freshwater	BREF for textiles page 49
Ethylenediaminetetraacetic acid (EDTA) (60-00-4)	Bleaching	Stable complexes with metals	Freshwater	BREF for textiles page 46
Nonylphenol ethoxylates (NPEOs)[401] (9016-45-9)	Scouring, washings (due to knitting and spinning)	Nonylphenol (NP) 25154-52-3	Freshwater	BREF for textiles page 415
Sodium chloride (7647-14-5)	Dyeing	Adsorbable organically bound halogens (AOX) - if mixed with hydrogen peroxide bleach wastewater e.g. trichloromethane (67-66-3); chloroacetic acid (79-11-8)	Freshwater	BREF for textiles page 48
Polysiloxane (161755-53-9)	Drying	Volatile organic compounds (VOCs)	Air (also indoor)	BREF for textiles page 860
1,2,4 – trichlorobenzene (120-82-1)	Drying	Polychlorinated dibenzodioxins/dibenzofurans (PCDD/Fs)	Air (also indoor)	BREF for textiles page 114
Sodium hypochlorite (7681-52-9)	Finishing	Adsorbable organically bound halogens (AOXs) e.g. trichloromethane (67-66-3); chloroacetic acid (79-11-8)	Freshwater	BREF for textiles page 110
Polymer (PA) based resin with epichlorohydrin (proxy with epichlorohydrin) 106-89-8	Finishing	Adsorbable organically bound halogens (AOX) e.g. trichloromethane (67-66-3); chloroacetic acid (79-11-8)	Freshwater	BREF for textiles page 111
Ammonium sulfate (7783-20-2)	Finishing, drying	Ammonia	Air (also indoor)	BREF for textiles page 245

Source: JRC's own elaboration.

Substances representativeness check

The data representativeness of **functional substances** was assessed with regard to:

- <u>Timeframe condition:</u> considering that the base year is 2019 and the lifespan of the selected product is 85 wears (corresponding to 6.6 years), the substances present were checked against product restrictions that were in force in 2012. For functional substances, no restricted substances that might possibly have been present in the inventory (e.g. Direct Black 38, CAS 1937-37-7) were selected for inclusion in the Base Case, according to the method defined to select substances in the Base Case (see Section A). Since the source of

[401] For the rationale for NPEOs inclusion in the Case Study, please refer to Table 42.

data found for Direct Black 38 is not recent[402] and the first marketing limitation of certain azocolorants in the EU, via Directive 2002/61/EC precedes the source considerably, this substance was not considered representative as a primary material in the Base Case. However, the presence of legacy Direct Black 38 may still appear in waste textiles and recycled cotton fibres, as a consequence of old clothing being recycled and potential non-compliant imports to the EU.

— Geographical condition: the supply chain of textiles is usually global; thus the materials and the product could be imported into the EU. Substances that are not used anymore in the EU manufacturing activities (because of relevant restrictions) are considered generally not to be present in the EU market, although in some instances the substance may be present in products due to failures in market surveillance.

— Technological condition: the conventional and non-optimised most commonly used application technologies are considered, relying on the analysis reported in the BREF for textiles, taking into account both past and present practices in substances management. Best Available Techniques (BAT) are not considered in this assessment, since it is performed under the worst-case assumption.

— The data representativeness of **non-intentionally added substances** was assessed with regard to:

  - Timeframe condition: considering that the base year is 2019 and the lifespan of the selected product is 85 wears (corresponding to 6.6 years), the chemicals present were checked against product restrictions that were present in 2012 (**Table 32**). A discussion and justification for their presence considering applicable restrictions is reported.

  - Geographical condition: given the supply chain of textiles is usually global, the materials and the product could be imported into the EU. Substances that are not used anymore in the EU manufacturing activities (because of relevant restrictions, e.g. REACH restriction on NPEOs in industrial and domestic detergents[403]) are considered to be possibly present in the product, taking into account restrictions that apply on NPEOs in imported products being placed on the market.

  - Technological condition: the state of the art and the most commonly used application technologies are considered, relying on the analysis reported in the BREF for textiles, taking into account both past and present practices in chemical management. However, Best Available Techniques (BAT) are not considered in this assessment, since it is performed under the worst-case assumption.

Box 7. Comments and lessons learnt from the testing on Section A: Preliminary steps for the method (focus on non-intentionally added substances and substances along the life cycle).

It is acknowledged that **great effort** will be required in mapping substances for this product group, because of the many functions that substances provide along the supply chain and because of the high data demand to estimate the variation of concentration of substances in materials and in the product from the manufacturing stage to the use stage.

402 ECHA, Annex XV SVHC dossier, "Proposal for identification of a substance as a CMR 1A or 1B, PBT, vPvB or a substance of an equivalent level of concern, C.I. DIRECT BLACK 38", https://echa.europa.eu/documents/10162/bd7d4cbe-2b14-4066-bbfc-6b7ec7422b92

403 ANNEX XVII TO REACH, Entry 46, (a) Nonylphenol, (b) Nonylphenol ethoxylates

The actual functions that are needed strongly depend on the final product and, since the **BREF for textiles does not focus on products** but rather on manufacturing processes of fibres and fabrics, it does not include either comprehensive or full information on actual functions of substances for each type of product. The BREF also ignores the presence of many substances in the final product, thus **primary sources of data** (textiles companies, consumer NGOs' evidence, etc) are suggested to be collected to fill these gaps.

From the **data modelling** in the testing, two chemicals (1,2,4-trichlorobenzene and cyclic trimers of ethylene terephthalate) listed as "impurities" in **Table 28** show high concentration % w/w in the materials compared to the other substances, respectively 3.42% and 3%. In particular, for the first chemical, the concentration is the result of a mass balance that also takes into account water emissions during dyeing, while for the second the data refers to fibre content (interpreted as input raw material rather than finished product) and no subsequent leaching was considered during washings given the low water solubility of the substance.

Table 32. NIAS representativeness check against relevant product restrictions.

Name (CAS number)	SVHC	ECHA Restriction	Applies to	Relevant concentration limit	Applicability date	Discussion and justification for inclusion in the BC
Nonyl phenol ethoxylates (NPEOs) (9016-45-9)	Yes	Regulation 26/2016 Entry 46a	Articles - textile sector specific	1. Shall not be placed on the market after 3 February 2021 in textile articles which can reasonably be expected to be washed in water during their normal lifecycle, in concentrations equal to or greater than **0.01 % by weight** of that textile article or of each part of the textile article. 2. Paragraph 1 shall not apply to the placing on the market of second- hand textile articles or of new textile articles produced, without the use of NPE, exclusively from recycled textiles.	2021	Restriction not affecting the chemicals composition of the BC at this stage of the assessment (product-related), since the year of production of the BC for this Case Study is 2012. However, this restriction (and related derogation) is relevant for the recycling scenario and for the recyclate used in a new product and it is discussed in next section.
N,N-dimethylacetamide (127-19-5)	Yes	Regulation 2018/1513 (carcinogenic, mutagenic or toxic for reproduction (CMR), category 1A or 1B), Entry 72	Article - textile sector specific	3000 mg/kg (= 0.3%) (after 1 November 2020)	2020	Restriction not affecting the chemicals composition of the BC, since the year for starting the collection of data for this Case Study is 2012.
Pentadecafluorooctanoic Acid (PFOA) (335-67-1)	Yes	Commission Delegated Regulation (EU) 2020/784 of 8 April 2020 amending Annex I to Regulation (EU) 2019/1021 of the European Parliament and of the Council as regards the listing of perfluorooctanoic acid (PFOA), its salts and PFOA-related compounds, OJ L 188I, 15.6.2020	substances, mixtures or articles	1. For the purposes of this entry, point (b) of Article 4(1) shall apply to concentrations of PFOA or any of its salts equal to or below **0,025 mg/kg (0,0000025 % by weight)** where they are present in substances, mixtures or articles. 2. For the purposes of this entry, point (b) of Article 4(1) shall apply to concentrations of any individual PFOA-related compound or a combination of PFOA-related compounds equal to or below 1 mg/kg (0,0001 % by weight) where they are present in substances, mixtures or articles	2020	The concentration considered as impurity in PTFE is defined according to the limit.

Source: JRC's own elaboration.

Focus on substances at the end-of-life scenarios

The aim of the testing in this section is to provide an overview about the end-of-life scenarios (EoLs) and issues related to substances. In particular, the final objective is to identify and if possible, to quantify the composition, especially in terms of SoCs, of the post-consumer waste, taking into account possible leakages during use stage and the effect of the waste management operations on the presence of substances (see **Figure 13**). Moreover, the composition of the recyclate is provided and discussed considering the inputs received from stakeholders (not publicly available).

The End-of-Life scenarios were defined according to available sources and are reported in **Table 33**.

Table 33. End-of-Life and related approximate mass fraction, i.e. the ratio between the mass of the treated/disposed waste Base Case and the total mass of the waste Base Case.

End of life scenario	Approx. mass fraction (%)
Mechanical recycling (insulation + wipers)	7%
Incineration	39.5%
Landfill	48%
Total End-of-Life scenarios	<100%

Source: JRC's own elaboration, based on and adapted from available sources.

Note: Approximate values are reported for sensitivity reasons. The total percentage does not sum up to 100% (as highlighted in red).

The incineration rate reported above is the sum of the rates of different types of incineration treatments that differ depending on the origin of the materials. The resulting share of waste materials treated by landfill and incineration was calculated considering that each material is recycled for 7% of its weight and that a different incineration is considered depending on the origin of the materials. The results are reported in **Table 34**.

Table 34. Share of post-consumer waste materials of the Base Case treated under the different End-of-Life scenarios. The mass fraction represents the ratio between the mass of the treated/disposed material and the total mass of the specific waste material.

Waste Material	Approx. mass fraction (%) for landfill	Approx. mass fraction (%) to incineration of bio-based	Approx. mass fraction (%) to incineration of synthetic	Approx. mass fraction (%) to recycling
Acrylic	36%	57%	-	7%
Cashmere	59%	-	34%	7%
Wool	59%	-	34%	7%
Nylon 6.6	36%	57%	-	7%
Polyester	36%	57%	-	7%
Recycled PET	36%	57%	-	7%
Cotton	59%	-	34%	7%
Viscose	59%	-	34%	7%

Source: JRC's own elaboration.

Depending on the calculated shares of the materials, it was possible to make assumptions regarding the fate of each substance associated to the materials, according to the End-of-Life scenarios, and its amount (**Table 35** and **Note:** according to inventory results, substances marked with an asterisk "*" are no longer present as they are released during domestic washing.

Table 36). However, for simplicity, no differences were envisaged between the different types of incinerations in terms of emissions, as explained in the following subsections.

Table 35. Functional substances in the post-consumer waste Base Case.

Substances	CAS	Material	Mass (g)	Concentration in waste material (%)	Concentration in waste product (%)	Set-up for calculation (i.e. mass balance/direct data on product) and sources
Disperse Blue 35	12222-75-2	Acrylic fibres	1.91E-04	<0.01%	<0.01%	Direct data on recycled materials from RI.SE, 2019[404] (proxy with post-consumer waste)
Polytetrafluoroethylene (PTFE)	9002-84-0	Acrylic fibres	7.92E-02	0.9%	0.03%	Mass balance, considering data about PFOA emissions – (van der Veen et al., 2022)[405]. Assumed the same reduction for PTFE since it contains PFOA as impurity.
(benzothiazol-2-ylthio)methyl thiocyanate; TCMTB	21564-17-0	Acrylic fibres	4.15E-04	<0.01%	<0.01%	Mass balance, considering emission data about emission of benzothiazole (Luongo et al., 2016)[406]
Reactive Blue 72	61968-93-2	Cashmere	1.85	8.23%	0.39%	Mass balance, with emissions data about reactive dye discharge (Zhao et al., 2022)
Polytetrafluoroethylene (PTFE)	9002-84-0	Cashmere	1.12E-01	0.5%	0.02%	Mass balance, considering data about PFOA emissions – (van der Veen et al., 2022). Assumed the same reduction for PTFE since it contains PFOA as impurity.
(benzothiazol-2-ylthio)methyl thiocyanate; TCMTB	21564-17-0	Cashmere	5.85E-04	<0.01%	<0.01%	Mass balance, considering emission data about emission of benzothiazole (Luongo et al., 2016)
Sodium hypochlorite*	7681-52-9	Cashmere	0	0%	0%	Mass balance, considering emission data about gradual release during washings from Kettlewell et al., 2015[407]
Polymer (PA) based resin with epichlorohydrin*	106-89-8	Cashmere	0	0%	0%	Mass balance, proxy with Dichloroisocyanurate (complementary function) from Kettlewell et al., 2015
Direct Orange 62	12222-38-7	Cotton	1.17E+01	6.27%	2.55%	Mass balance, considering emission data about reactive dye discharge - proxy (Zhao et al., 2022)
Formaldehyde, reaction products with melamine*	94645-56-4	Cotton	0	0%	0%	Mass balance, considering data about emissions of formaldehyde from Piccinini et al., 2007 and number of washes of the Base

[404] Research Institute of Sweden (RI.SE), REPORT Results of analyses for Classification and risk assessment of textiles for material recycling – Funded by Vinnova 2017- 2019, https://www.ri.se/sites/default/files/2020-11/Classification%20and%20risk%20assessment_analytical%20results.pdf.

[405] van der Veen, I., Schellenberger, St., Hanning, A. C., Stare, A., de Boer, J., Weiss, J. M., Leonards, P. E. G., Fate of Per- and Polyfluoroalkyl Substances from Durable Water-Repellent Clothing during Use, Environmental Science & Technology, 2022, M3 - doi: 10.1021/acs.est.1c07876.

[406] Luongo, G., Avagyan, R., Hongyu, R. et al. The washout effect during laundry on benzothiazole, benzotriazole, quinoline, and their derivatives in clothing textiles. Environ Sci Pollut Res 23, 2537–2548 (2016). https://doi.org/10.1007/s11356-015-5405-7.

[407] R. Kettlewell , A. De Boos , J. Jackson, Commercial shrink-resist, finishes for wool, 2015, Australian Wool Innovation Limited , Sydney, NSW, Australia, chapter in Functional Finishes for Textiles Improving Comfort, Performance and Protection, A volume in Woodhead Publishing Series in Textiles, https://www.sciencedirect.com/book/9780857098399/functional-finishes-for-textiles?via=ihub=.

Substances	CAS	Material	Mass (g)	Concentration in waste material (%)	Concentration in waste product (%)	Set-up for calculation (i.e. mass balance/direct data on product) and sources
						Case (the total amount on the Base Case would be emitted)
Hexa(methoxymethyl)melamine*	3089-11-0	Cotton	0	0%	0%	Mass balance, considering data about emissions of formaldehyde from Piccinini et al., 2007 and number of washes of the Base Case (the total amount on the Base Case would be emitted)
Polytetrafluoroethylene (PTFE)	9002-84-0	Cotton	9.48E-01	0.51%	0.21%	Mass balance, considering data about PFOA emissions – (van der Veen et al., 2022). Assumed the same reduction for PTFE since it contains PFOA as impurity.
(benzothiazol-2-ylthio)methyl thiocyanate; TCMTB	21564-17-0	Cotton	4.97E-03	<0.01%	<0.01%	Mass balance, considering emission data about emission of benzothiazole (Luongo et al., 2016)
Reactive Blue 72	61968-93-2	Nylon 6.6	5.26E-01	7.62%	0.11%	Mass balance, with emissions data about reactive dye discharge (Zhao et al., 2022)
Polytetrafluoroethylene (PTFE)	9002-84-0	Nylon 6.6	3.16E-02	0.46%	0.01%	Mass balance, considering data about PFOA emissions – (van der Veen et al., 2022). Assumed the same reduction for PTFE since it contains PFOA as impurity.
(benzothiazol-2-ylthio)methyl thiocyanate; TCMTB	21564-17-0	Nylon 6.6	1.66E-04	<0.01%	<0.01%	Mass balance, considering emission data about emission of benzothiazole (Luongo et al., 2016)
Disperse Blue 35	12222-75-2	Polyester fibres	8.26E-04	<0.01%	<0.01%	Direct data on recycled materials from RI.SE, 2019 (proxy with post-consumer waste)
Polytetrafluoroethylene (PTFE)	9002-84-0	Polyester fibres	3.43E-01	0.49%	0.08%	Mass balance, considering data about PFOA emissions – (van der Veen et al., 2022). Assumed the same reduction for PTFE since it contains PFOA as impurity.
(benzothiazol-2-ylthio)methyl thiocyanate; TCMTB	21564-17-0	Polyester fibres	1.80E-03	<0.01%	<0.01%	Mass balance, considering emission data about emission of benzothiazole (Luongo et al., 2016)
Decabromodiphenyl ethane (DBDPE)	84852-53-9	Recycled PET fibres	2.08	16.07%	0.45%	*Since it is in the matrix, it is supposed to be not washed away*
Disperse Blue 35	12222-75-2	Recycled PET fibres	1.52E-04	<0.01%	<0.01%	Direct data on recycled materials from RI.SE, 2019 (proxy with post-consumer waste)
Polytetrafluoroethylene (PTFE)	9002-84-0	Recycled PET fibres	6.33E-02	0.49%	0.01%	Mass balance, considering data about PFOA emissions – (van der Veen et al., 2022). Assumed the same reduction for PTFE since it contains PFOA as impurity.
(benzothiazol-2-ylthio)methyl thiocyanate; TCMTB	21564-17-0	Recycled PET fibres	3.32E-04	<0.01%	<0.01%	Mass balance, considering emission data about emission of benzothiazole (Luongo et al., 2016)
Direct Orange 62	12222-38-7	Viscose	4.75E-01	6.27%	0.10%	Mass balance, considering emission data about reactive dye discharge - proxy (Zhao et al., 2022)
Formaldehyde, reaction products with melamine*	94645-56-4	Viscose	0	0%	0%	Mass balance, considering data about emissions of formaldehyde from Piccinini et al., 2007
Hexa(methoxymethyl)melamine*	3089-11-0	Viscose	0	0%	0%	Mass balance, considering data about emissions of formaldehyde from Piccinini et al., 2007 and

Substances	CAS	Material	Mass (g)	Concentration in waste material (%)	Concentration in waste product (%)	Set-up for calculation (i.e. mass balance/direct data on product) and sources
						number of washes of the Base Case (the total amount on the Base Case would be emitted)
Polytetrafluoroethylene (PTFE)	9002-84-0	Viscose	3.86E-02	0.51%	0.01%	Mass balance, considering data about PFOA emissions – (van der Veen et al., 2022). Assumed the same reduction for PTFE since it contains PFOA as impurity.
(benzothiazol-2-ylthio)methyl thiocyanate; TCMTB	21564-17-0	Viscose	2.03E-04	<0.01%	<0.01%	Mass balance, considering emission data about emission of benzothiazole (Luongo et al., 2016)
Titanium dioxide	13463-67-7	Viscose	7.58E-02	1.00%	0.02%	It is assumed that the chemical is not emitted because it is incorporated into the fibre and long-lasting to washings.[408]
Reactive Blue 72	61968-93-2	Wool	1.11E+01	8.23%	2.32%	Mass balance, with emissions data about reactive dye discharge (Zhao et al., 2022)
Polytetrafluoroethylene (PTFE)	9002-84-0	Wool	6.69E-01	0.50%	0.15%	Mass balance, considering data about PFOA emissions – (van der Veen et al., 2022). Assumed the same reduction for PTFE since it contains PFOA as impurity.
(benzothiazol-2-ylthio)methyl thiocyanate; TCMTB	21564-17-0	Wool	3.51E-03	<0.01%	<0.01%	Mass balance, considering emission data about emission of benzothiazole (Luongo et al., 2016)
Sodium hypochlorite*	7681-52-9	Wool	0	0%	0%	Mass balance, considering emission data about gradual release during washings from Kettlewell et al., 2015[409]
Polymer (PA) based resin with epichlorohydrin*	106-89-8	Wool	0	0%	0%	Mass balance, proxy with Dichloroisocyanurate (complementary function) from Kettlewell et al., 2015

Source: JRC's own elaboration.

Note: according to inventory results, substances marked with an asterisk "*" are no longer present as they are released during domestic washing.

Table 36. Non-intentionally added substances in the post-consumer waste BC.

Substances	CAS	Material (input/final)	Mass (g)	Concentration in material (%)	Concentration in product (%)
Nonyl phenol ethoxylates (NPEOs)*	9016-45-9	Acrylic fibres (input)	0	0%	0%
White mineral oil	8042-47-5	Acrylic fibres	5.61E-02	0.35%	0.01%
Polyciclic aromatic hydrocarbons (PAH) e.g. naphthalene	91-20-3	Acrylic fibres (input)	3.99E-04	<0.01%	<0.01%
1,2,4 – trichlorobenzene	120-82-1	Acrylic fibres (final)	5.93E-01	3.70%	0.13%

408 Textile RnD, https://textilernd.com/eco-friendly-textiles-how-dope-dyeing-makes-a-difference/.

409 R. Kettlewell , A. De Boos , J. Jackson, Commercial shrink-resist, finishes for wool, 2015, Australian Wool Innovation Limited , Sydney, NSW, Australia, chapter in Functional Finishes for Textiles Improving Comfort, Performance and Protection, A volume in Woodhead Publishing Series in Textiles, https://www.sciencedirect.com/book/9780857098399/functional-finishes-for-textiles?via=ihub=.

Substances	CAS	Material (input/final)	Mass (g)	Concentration in material (%)	Concentration in product (%)
N,N-dimethylacetamide	127-19-5	Acrylic fibres	1.72E-05	<0.01%	<0.01%
Pentadecafluorooctanoic Acid (PFOA)	335-67-1	Acrylic fibres (final)	2.02E-09	<0.01%	<0.01%
Nonyl phenol ethoxylates (NPEOs)*	9016-45-9	Cashmere (input)	0	0%	0%
White mineral oil	8042-47-5	Cashmere (input)	7.77E-02	0.35%	0.02%
Polycyclic aromatic hydrocarbons (PAH) e.g. naphthalene	91-20-3	Cashmere (input)	5.61E-04	<0.01%	<0.01%
1,2,4 – trichlorobenzene	120-82-1	Cashmere (final)	8.35E-01	3.76%	0.18%
Pentadecafluorooctanoic Acid (PFOA)	335-67-1	Cashmere (final)	2.80E-09	<0.01%	<0.01%
Copper - free metal impurity - not bound in the colourant	7440-50-8	Cashmere (final)	4.74E-04	<0.01%	<0.01%
Nonyl phenol ethoxylates (NPEOs)*	9016-45-9	Cotton (input)	0	0%	0%
White mineral oil	8042-47-5	Cotton (input)	6.44E-01	0.35%	0.14%
Polycyclic aromatic hydrocarbons (PAH) e.g. naphthalene	91-20-3	Cotton (input)	4.77E-03	<0.01%	<0.01%
Pentadecafluorooctanoic Acid (PFOA)	335-67-1	Cotton(final)	2.33E-08	<0.01%	<0.01%
Nonyl phenol ethoxylates (NPEOs)*	9016-45-9	Nylon 6.6 (input)	0	0%	0%
White mineral oil	8042-47-5	Nylon 6.6 (input)	2.37E-02	0.35%	0.01%
Polycyclic aromatic hydrocarbons (PAH) e.g. naphthalene	91-20-3	Nylon 6.6 (input)	1.59E-04	<0.01%	<0.01%
Antimony trioxide	1309-64-4	Nylon 6.6 (input)	1.62E-03	0.02%	<0.01%
Cyclic trimers of ethylene terephthalate	7441-32-9	Nylon 6.6 (input)	2.08E-01	3.05%	0.04%
Pentadecafluorooctanoic Acid (PFOA)	335-67-1	Nylon 6.6 (final)	8.54E-10	<0.01%	<0.01%
Copper - free metal impurity - not bound in the colourant	7440-50-8	Nylon 6.6 (input)	1.34E-04	<0.01%	<0.01%
Nonyl phenol ethoxylates (NPEOs)*	9016-45-9	Polyester fibres (input)	0	0%	0%
White mineral oil	8042-47-5	Polyester fibres (input)	2.43E-01	0.35%	0.05%
Polycyclic aromatic hydrocarbons (PAH) e.g. naphthalene	91-20-3	Polyester fibres (input)	1.73E-03	<0.01%	<0.01%
1,2,4 – trichlorobenzene	120-82-1	Polyester fibres (final)	2.57	3.70%	0.57%
Antimony trioxide	1309-64-4	Polyester fibres (input)	1.76E-02	0.03%	<0.01%

Substances	CAS	Material (input/final)	Mass (g)	Concentration in material (%)	Concentration in product (%)
Cyclic trimers of ethylene terephthalate	7441-32-9	Polyester fibres (input)	2.25E+00	3.26%	0.48%
Pentadecafluorooctanoic Acid (PFOA)	335-67-1	Polyester fibres (final)	8.77E-09	<0.01%	<0.01%
Nonyl phenol ethoxylates (NPEOs)*	9016-45-9	R-PET (input)	0	0%	0%
White mineral oil	8042-47-5	R-PET (input)	4.48E-02	0.35%	0.01%
Polycicilic aromatic hydrocarbons (PAH) e.g. naphthalene	91-20-3	R-PET (input)	3.19E-04	<0.01%	<0.01%
Volatile organic compounds (VOC) e.g. Benzaldehyde	100-52-7	R-PET (input)	2.11E-05	<0.01%	<0.01%
1,2,4 – trichlorobenzene	120-82-1	R-PET (final)	4.74E-01	3.70%	0.10%
Pentadecafluorooctanoic Acid (PFOA)	335-67-1	R-PET (final)	1.62E-09	<0.01%	<0.01%
Antimony trioxide	1309-64-4	R-PET (input)	3.24E-03	0.03%	<0.01%
Cyclic trimers of ethylene terephthalate	7441-32-9	R-PET (input)	4.15E-01	3.26%	0.09%
Nonyl phenol ethoxylates (NPEOs)*	9016-45-9	Viscose (input)	0	0%	0%
White mineral oil	8042-47-5	Viscose (input)	2.62E-02	0.35%	0.01%
Polycicilic aromatic hydrocarbons (PAH) e.g. naphthalene	91-20-3	Viscose (input)	1.94E-04	<0.01%	<0.01%
Pentadecafluorooctanoic Acid (PFOA)	335-67-1	Viscose (final)	9.48E-10	<0.01%	<0.01%
Nonyl phenol ethoxylates (NPEOs)*	9016-45-9	Wool (input)	0	0%	0%
White mineral oil	8042-47-5	Wool (input)	4.66E-01	0.35%	0.10%
Polycicilic aromatic hydrocarbons (PAH) e.g. naphthalene	91-20-3	Wool (input)	3.37E-03	<0.01%	<0.01%
1,2,4 – trichlorobenzene	120-82-1	Wool (final)	5.01	3.76%	1.11%
Pentadecafluorooctanoic Acid (PFOA)	335-67-1	Wool (final)	1.68E-08	<0.01%	<0.01%
Copper - free metal impurity - not bound in the colourant	7440-50-8	Wool (final)	2.84E-03	<0.01%	<0.01%

Source: JRC's own elaboration.

Note: according to inventory results, substances marked with an asterisk "*" are no longer present as they are released during domestic washing.

Additional insights regarding the waste management operations and issues related to substances are reported below for each EoL scenario. For this purpose, the information contained in the following sources was considered:

— the Joint Research Centre (JRC) report "Techno-scientific assessment of the management options for used and waste textiles in the European Union" (Huygens et al., 2023)[410], considered for the assessment of the waste flows;

— the Joint Research Centre (JRC) report "Circular economy perspectives in the EU Textile sector, Final report" (Köhler et al., 2021)[411], considered for the assessment of the waste flows;

— the study "Study on the technical, regulatory, economic and environmental effectiveness of textile fibres recycling" (Duhoux et al., 2021)[412], considered for the technical description of the pre-recycling and recycling processes.

The above-mentioned reports were complemented with inputs from stakeholders regarding specific issues.

1. Collection schemes and waste flows

The collection of the post-consumer textile waste is mainly separately performed in dedicated collection bins, representing approximately 38% of textiles placed on the EU market (Köhler et al., 2021). The remaining fraction, not captured by separate collection, is disposed of in landfills or incinerated with energy recovery.

Possible issues related to substances:

Contamination could occur when different textile waste flows are mixed together during collection, thus leading to the presence of new chemicals on the Base Case compared to those mapped in the testing of Section A for the present Case Study. However, the extent of this contamination is assumed to be limited.

2. Sorting

Sorting is mainly performed **manually**, because of the current technological limitations of automated sorting, e.g. near-infrared spectroscopy (NIR) can be limited by finishings and coatings and it is not able to distinguish (complex) material blends, such as elastane-containing yarns (Duhoux et al., 2021).

According to Huygens et al. (2023) sorting is mainly performed in third countries, in particular in the Asian continent, because of lower labour costs in these countries. The above techniques and practices were confirmed by inputs from stakeholders, that reported that Asian sorting companies perform the preparation for recycling, consisting in the elimination of interfering elements (e.g. labels, buttons) and in the separation of materials by composition and colour. Stakeholders reported also that during sorting, wastes originating from different countries are mixed together since post-consumer waste is collected worldwide (e.g. from the US).

Possible issues related to substances:

Two main issues should be highlighted:

— Post-consumer textile **waste flows from extra-EU countries** may carry chemicals from the manufacturing and use phases that are not compliant with current EU restrictions on products (i.e. they may contain legacy chemicals), potentially limiting the use of the final

[410] Huygens, D., Foschi, J., Caro, D., Caldeira, C., Faraca, G., Foster, G., Solis, M., Marschinski, R., Napolano, L., Fruergaard Astrup, T. and Tonini, D., *Techno-scientific assessment of the management options for used and waste textiles in the European Union.* Publications Office of the European Union, Luxembourg, 2023, doi:10.2760/6292, JRC134586.

[411] Köhler A., Watson D., Trzepacz S., Löw C., Liu R., Danneck J., Konstantas A., Donatello S. & Faraca G., 2021. *Circular Economy Perspectives in the EU Textile sector*, EUR 30734 EN, Publications Office of the European Union, Luxembourg, 2021, ISBN 978-92-76-38646-9, doi:10.2760/858144, JRC125110.

[412] Duhoux, T., Maes, E., Hirschnitz-Garbers, M., Peeters, K., Asscherickx, L., Christis, M., Stubbe, B., Colignon, P., Hinzmann, M., Sachdeva, A., VITO, CENTEXBEL, ecologic, Study on the technical, regulatory, economic and environmental effectiveness of textile fibres recycling, Final report, 2021, 10.2873/828412.

recyclate in new products. The case of NPEOs was highlighted by some stakeholders as particularly concerning, and is further discussed below in point 4 "Mapping the recycling options and barriers for the base case";

- The absence of EU-wide end-of-waste criteria for textiles (currently under development by the European Commission) means that the issues described above are not yet adequately addressed. Some stakeholders report that, after substantial economic and time-related investment in testing the recyclate destined for production of new products, the risk of the presence of legacy substances remains, i.e. those substances that would lead to the material being discarded. Overall, while it is expected that setting of the end-of-waste status would enhance the circularity of textiles, it is also recognised that the recycled fibre / yarn that is placed on the market will have to comply with the relevant restrictions / limitations in place, regardless of where the end-of-waste point is placed.

3. Mapping the reuse options and barriers for the base case

Reuse is not part of the End-of-Life scenarios considered, since it applies to products that have never become waste (i.e. they have not been discarded and thus were never collected as "waste").

For products (garments or apparel) that never reached the waste status, hereafter referred to as "second-hand textiles", the following options are common practice in the EU (Köhler et al., 2021):

- "Informal passing on of clothing between relatives or friends.
- Formal customer-to-customer (C2C) exchanges via physical flea-markets and online exchange platforms.
- Purchases of second-hand products via second-hand retailers, either in physical shops or online that may have either been sourced from domestic collection of used textiles, or from imports of used textiles".

Possible issues related to substances:

Second-hand textiles may contain substances deriving from the manufacturing and the use stages that are not compliant with current EU legislation and restrictions on products. Much of EU product-related legislation, and "chemicals-related" restrictions do not apply to second-hand products in the EU, and therefore there is a risk that these products might possibly carry legacy substances and could enter into the EU. The presence of legacy substances limit the use of the final recyclate from a new product, once it reaches the end of its life, and this complication would also apply in a diminished form, once the second-hand textile (that used recyclate as part of its 'ingredients') ultimately reached the end of the second life. These concerns would likely apply to successive life cycles, albeit in ever-diminishing percentages of legacy chemicals content. Reuse and preparation for reuse were not further analysed in the present Case Study for simplicity, since limited information were available regarding substances in reuse and preparation for reuse.

4. Mapping the recycling options and barriers for the Base Case

In the present Case Study, the recycling operations were assumed to occur only in the EU, in order to confine the discussion on barriers to circularity within the EU.

According to Huygens et al. (2023), the textile fraction that after sorting does not meet the quality requirements for (preparing for) re-use is mostly **mechanically recycled.** That is recycled for further use as cleaning rags or non-woven materials for different applications (e.g. insulation material for construction or the automotive sector), either within or outside the EU. Fibre-to-fibre recycling is very limited, as reported also in **Table 33**.

However, according to inputs from stakeholders, **fibre-to-fibre recycling** does occur for some specific materials. Stakeholders confirm that recycling is mainly performed mechanically, via shredding.

In the mechanical recycling process **little use of chemicals** is made or it may be totally absent. If chemicals are used, they could be e.g. ozone, detergents, bleaching agents, organic solvents, etc. (Duhoux et al., 2021).

Stakeholders report that **washing operations are very limited**, thus pre-treatments to remove undesired dyes are not performed, since the different textiles are separated by colour during sorting. This practice prevents the release of regulated chemicals, for example chemicals with a specific limit under the Water Framework Directive, such as the NPEOs, i.e. given the absence/limited use of washing operations, to streamline the Case Study, no water consumption for recycling is assumed.

Possible issues related to substances:

It is likely that substances present in the waste textile material are not removed via mechanical recycling processes and therefore they will stay in the recyclate.

Some substances were assessed to hinder recyclability from a technical point of view, and they are reported in the testing of Section B.

4.1 Assessment of the substances present in the recyclate

The chemical composition of the recyclate might be subject to changes, compared to that of the product per se, due to two possible differentiated events occurring during end-of-life processes/management:

1. During treatment of post-consumer waste, as a result of the mixing and resulting share of the original materials of the Base Case in the End-of-Life operations, and as a result of emissions taking place therein;
2. During End-of-Life operations as a consequence of cross-contamination from different waste streams.

In the first case, the substances present do not change compared to the chemical composition of the post-consumer waste (prior to the End-of-Life operations), but their relative amounts change according to the shares of the different waste materials subjected to the End-of-Life operations (**Table 34**). As reported above, no chemical emissions are considered to occur during mechanical recycling and for simplicity substances are assumed to remain in the recyclate.

In the second case, new materials and substances could end up in the recyclate because of the interaction between different waste streams. A separate assessment is reported below.

The **chemical composition of the recyclate** is reported in **Table 37**. The substances considered below relate to the **first case** described above.

Table 37. Substances composition of the recyclate relevant to the Base Case (first case).

Functional substances	CAS number	Process from previous life-cycle	Material	Mass (g)	Concentration in recyclate (%)
Disperse Blue 35	12222-75-2	Dyeing	Acrylic	1.31E-05	<0.01%
Polytetrafluoroethylene (PTFE)	9002-84-0	Finishing	Acrylic	5.45E-03	0.49%
(benzothiazol-2-ylthio)methyl thiocyanate; TCMTB	21564-17-0	Finishing	Acrylic	2.86E-05	<0.01%
Reactive Blue 72	61968-93-2	Dyeing	Cashmere	1.28E-01	8.23%
Polytetrafluoroethylene (PTFE)	9002-84-0	Finishing	Cashmere	7.68E-03	0.50%
(benzothiazol-2-ylthio)methyl thiocyanate; TCMTB	21564-17-0	Finishing	Cashmere	4.03E-05	<0.01%
Sodium hypochlorite*	7681-52-9	Finishing	Cashmere	0	0%

Functional substances	CAS number	Process from previous life-cycle	Material	Mass (g)	Concentration in recyclate (%)
Polymer (PA) based resin with epichlorohydrin*	106-89-8	Finishing	Cashmere	0	0%
Direct Orange 62	12222-38-7	Dyeing	Cotton	8.03E-01	6.27%
Formaldehyde, reaction products with melamine*	94645-56-4	Dyeing	Cotton	0	0%
Hexa(methoxymethyl)melamine*	3089-11-0	Finishing	Cotton	0	0%
Polytetrafluoroethylene (PTFE)	9002-84-0	Finishing	Cotton	6.52E-02	0.51%
(benzothiazol-2-ylthio)methyl thiocyanate; TCMTB	21564-17-0	Finishing	Cotton	3.42E-04	<0.01%
Reactive Blue 72	61968-93-2	Dyeing	Nylon 6.6	3.62E-02	7.62%
Polytetrafluoroethylene (PTFE)	9002-84-0	Finishing	Nylon 6.6	2.18E-03	0.46%
(benzothiazol-2-ylthio)methyl thiocyanate; TCMTB	21564-17-0	Finishing	Nylon 6.6	1.14E-05	<0.01%
Disperse Blue 35	12222-75-2	Dyeing	Polyester	5.69E-05	<0.01%
Polytetrafluoroethylene (PTFE)	9002-84-0	Finishing	Polyester	2.36E-02	0.49%
(benzothiazol-2-ylthio)methyl thiocyanate; TCMTB	21564-17-0	Finishing	Polyester	1.24E-04	<0.01%
Decabromodiphenyl ethane (DBDPE)	84852-53-9	Raw material production	Recycled PET	1.43E-01	15.08%
Disperse Blue 35	12222-75-2	Dyeing	Recycled PET	1.05E-05	<0.01%
Polytetrafluoroethylene (PTFE)	9002-84-0	Finishing	Recycled PET	4.36E-03	0.49%
(benzothiazol-2-ylthio)methyl thiocyanate; TCMTB	21564-17-0	Finishing	Recycled PET	2.28E-05	<0.01%
Direct Orange 62	12222-38-7	Dyeing	Viscose	3.27E-02	6.27%
Formaldehyde, reaction products with melamine*	94645-56-4	Dyeing	Viscose	0	0%
Hexa(methoxymethyl)melamine*	3089-11-0	Finishing	Viscose	0	0%
Polytetrafluoroethylene (PTFE)	9002-84-0	Finishing	Viscose	2.66E-03	0.51%
(benzothiazol-2-ylthio)methyl thiocyanate; TCMTB	21564-17-0	Finishing	Viscose	1.39E-05	<0.01%
Titanium dioxide	13463-67-7	Fibre production	Viscose	5.79E-03	1.00%
Reactive Blue 72	61968-93-2	Dyeing	Wool	7.65E-01	8.23%
Polytetrafluoroethylene (PTFE)	9002-84-0	Finishing	Wool	4.61E-02	0.50%
(benzothiazol-2-ylthio)methyl thiocyanate; TCMTB	21564-17-0	Finishing	Wool	2.42E-04	<0.01%
Sodium hypochlorite*	7681-52-9	Finishing	Wool	0	0%
Polymer (PA) based resin with epichlorohydrin*	106-89-8	Finishing	Wool	0	0%

Source: JRC's own elaboration.

Note: according to inventory results, substances marked with an asterisk "*" are no longer present as they are released during domestic washing

Substances that relate to the **second case** described above are discussed below, taking into account inputs received from stakeholders.

Stakeholders reported that, due to the global value chain of textiles, specific material flows from extra-EU countries enter the EU after the sorting step at End-of-Life. This information could be further investigated by retrieving official data on the amount of extra-EU post-consumer textiles that enters the EU, to properly capture the extent of the issue. The subsequent recycling process is understood to occur in the EU.

In these materials flows, the presence of NPEOs is reported by stakeholders to be the most concerning barrier to circularity. NPEOs in waste textile materials are derived mainly from the use phase (i.e. domestic washings) of products in extra-EU countries, where the restriction on NPEOs in industrial and domestic detergents is not always in place[413].

NPEOs are very soluble in water, and, according to stakeholders, they are released from the fibres and, at the same time, recharged in the fibres from the use of detergents at each domestic washing.

Stakeholders report that the final product when made with a blend of textile recyclate and virgin fibres of the same material type (i.e. wool) (the latter are used in order to ensure the material workability during the manufacturing of the fabric as well as a higher durability of the product[414]) carries a concentration of NPEOs that exceeds the limits prescribed under the current REACH restriction (Entry 46a). According to the REACH restriction that is in force, NPEOs:

"1. Shall not be placed on the market after 3 February 2021 in textile articles which can reasonably be expected to be washed in water during their normal lifecycle, in concentrations equal to or greater than 0.01 % by weight of that textile article or of each part of the textile article.

2. Paragraph 1 shall not apply to the placing on the market of second- hand textile articles or of new textile articles produced, without the use of NPE, exclusively from recycled textiles."

Stakeholders report that they are able to comply with REACH restriction on products that contain wool only relying on the derogation, i.e. mixing two different types of recycled fibres. From a circularity perspective, the presence of blends of materials, rather than a mono-material product, could generally lead to a decreased level of recyclability in textiles. Other wool recyclers' claims report that compliance with the limit of 0.01% is even almost impossible since the legacy content of NPE is high (mostly due to the features of the wool fibres).

The case described above clearly shows that trade-offs may have to be made to reconcile zero-pollution and increased circularity ambitions. Moreover, some stakeholders reported that they face limitations imposed by customers who are reluctant to rely on the derogation for material made exclusively from recycled textiles.

4.2 Assessment of landfill/incineration options

Landfilling and incineration End of Life options are considered in the Case Study, since they represent the principal destination for waste textiles presently, according to the available sources and literature.

<u>Possible issues related to substances:</u>

The issues here reported entail the fate of substances disposed via landfilling and incineration.

In particular, in the case of landfilling, there is an emerging concern about Perfluoroalkyl substances (PFAS) entering groundwater and freshwater[415]. Thus, as a conservative approach, in the present Case Study the assessment is conducted up to the quantification of the emissions that

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413 Unlike in the EU, where they were restricted under Council Directive Council Directive 76/769/EEC since 2003, and applicable from 17 January 2005. These restrictions were subsequently taken up and expanded as currently reflected by entries 46 and 46a in Annex XVII to REACH.

414 https://www.woolwise.com/wp-content/uploads/2017/07/Wool-482-582-08-T-02.pdf.

415 Masoner, J. R., Kolpin, D. W., Cozzarelli, I. M., Smalling, K. L., Bolyard, S. C., Field, J. A., Furlong, E. T., Gray, J. L., Lozinski, D., Reinhart, D., Rodowa, A., Bradley, P. M., Landfill leachate contributes per-/poly-fluoroalkyl substances (PFAS) and pharmaceuticals to municipal wastewater, Environmental Science: Water Research & Technology, 2020, http://dx.doi.org/10.1039/D0EW00045K

could occur after disposal (**Table 38**). For emissions due to landfilling, following the worst-case approach, the number of substances present in the waste material is assumed to be emitted undegraded into water[416].

Table 38. Emissions from the landfilled fraction of the Base Case to water.

Substances	Type	Material	Mass of substances to landfill (assumed all as water emission) (g)
Disperse Blue 35	Functional substance	Acrylic, polyester, recycled PET	4.24E-04
Polytetrafluoroethylene (PTFE)	Functional substance	All	1.23E+00
(benzothiazol-2-ylthio)methyl thiocyanate; TCMTB	Functional substance	All	6.46E-03
Reactive Blue 72	Functional substance	Cashmere, wool, nylon 6.6	7.85
Direct Orange 62	Functional substance	Cotton, viscose	7.16
Decabromodiphenyl ethane (DBDPE)	Functional substance	Recycled PET	7.52E-01
Titanium dioxide	Functional substance	Viscose	4.47E-02
White mineral oil	NIAS	All	8.50E-01
Polycyclic aromatic hydrocarbons (PAH) e.g. naphthalene	NIAS	All	6.20E-03
Volatile organic compounds (VOC) e.g. benzaldehyde	NIAS	Recycled PET	7.66E-06
1,2,4 – trichlorobenzene	NIAS	Polyester, recycled PET, acrylic	6.89E-01
Antimony trioxide	NIAS	Polyester, recycled PET, nylon 6.6	8.13E-03
Cyclic trimers of ethylene terephthalate	NIAS	Polyester, recycled PET, nylon 6.6	1.04
N,N-dimethylacetamide	NIAS	Acrylic	6.21E-06
Copper	NIAS	Wool, cashmere, nylon 6.6	2.01E-03

Source: JRC's own elaboration.

As regards emissions due to incineration, the BREF for textiles reports that thermal degradation of flame retardants and chlorinated compounds could generate dioxins and furans. There are reports in the scientific literature providing air emissions due to co-incineration of textile industrial waste (Ying et al., 2022)[417] . These authors report that Polychlorinated dibenzodioxins/dibenzofurans (PCDD/Fs) are emitted, as well as additional pollutants, and that PCDD/Fs are present in the fly ash at the fabric filter (which is then subsequently solidified and afterwards buried in a landfill). The main reported data concerning operational conditions of relevant incineration plant are reported in **Table 39**. No data on the chemical composition of the textile waste are available, thus, emissions concentration data are assumed as a proxy in the Case Study. The concentration data have been converted to calculate the emissions for the fraction of Base Case that is incinerated, for both

416 Further assessments could be considered to properly address freshwater emissions and groundwater emissions.

417 Yuxuan Ying, Yunfeng Ma, Xiaoxiao Wang, Hong Yu, Angjian Wu, Shengyong Lu, Xiaodong Li, Xiaoqing Lin, Lijun Liu, Wenhua Yin, Emission, partition, and formation pathway of polychlorinated dibenzo-p-dioxins and dibenzofurans during co-disposal of industrial waste with municipal solid waste, Journal of Environmental Chemical Engineering, Volume 11, Issue 1, 2023, https://doi.org/10.1016/j.jece.2022.109242.

exhaust air (**Table 40**) and fly ash (disposed of in a landfill after solidification has been applied) (**Table 41**).

Table 39. Operational conditions of the representative incineration plant considered.

Exhaust gas (Nm^3/h)	Textile rate (t/h)	Fly ashes rate (t/h)
52000	2.44	3.75

Source: Ying et al., 2022.

Note: the paper refers to a research conducted at a full-scale MSWI plant in Jiangsu, Province of Southeastern China.

Table 40. Concentration at the stack for Base Case incinerated and emissions

Substance (concentration unit of measure)	CAS number	Concentration value at the chimney (Ying et al., 2022)	Amount for kg of textile (g/kg)	Amount emission for the Base Case (g)
Sum PCDD/Fs (ng I-TEQ/Nm^3)	51207-31-9; 1746-01-6[418]	0.04	8.52E-10	5.49E-11
CO (mg/Nm^3)	630-08-0	0.43	9.16E-06	5.90E-07
NOx (mg/Nm^3)	11104-93-1	120.64	2.57E-03	1.66E-04
SO_2 (mg/Nm^3)	7446-09-5	13.25	2.82E-04	1.82E-05
HCl (mg/Nm^3)	7647-01-0	4.38	9.33E-05	6.01E-06
PM (mg/Nm^3)	-	1.96	4.18E-05	2.69E-06

Source: JRC's own elaboration based on Ying et al., 2022.

Note: the paper refers to a research conducted at a full-scale MSWI plant in Jiangsu, Province of Southeastern China.

Table 41. Concentration in the fly ash for Base Case textile waste and emissions amounts (in landfilling ashes)

Substance (concentration unit of measure)	Concentration in the fly ashes at the filter	Amount paper (g/kg)	Amount BASE CASE (g)
Sum PCDD/Fs (ng I-TEQ/kg)	490.36	7.54E-07	4.86E-08

Source: JRC's own elaboration based on Ying et al., 2022.

Note: the paper refers to a research conducted at a full-scale MSWI plant in Jiangsu, Province of Southeastern China.

418 Two CAS numbers are assumed for PCDD, i.e. Dibenzofuran, 2,3,7,8-tetrachloro- and 2,3,7,8-tetrachlorodibenzo[b,e][1,4]dioxin.

Box 8. Comments and lessons learnt from the testing on Section A: Preliminary steps for the method (focus on end-of-life stage).

Two main challenges and limitations were present for the modelling of substances at the end of life: firstly, the amounts of **substances present in the recyclate had to be calculated for each material**, while noting that this separation may not reflect reality, i.e. the different types of fibres may often not be separated. Similarly, the shares of the waste in the different end of life scenarios are also not based on measurements, but instead have been derived via an allocation, based on statistical data.

Secondly, the definition of the fate of substances at the end-of-life would require a deeper **understanding of the physico-chemical processes** of such substances depending on the type of waste treatment applied. While the mass balance calculation was applied in the testing for the landfilling (i.e. the same substances in incoming waste are emitted, to some extent, to freshwater), this could not be ensured for incineration, where emissions of substances in the Base Case were defined based on literature, rather than the actual composition of the waste. However, the authors recognize that determining a sound correspondence between substances in the incoming waste and emissions deriving from the treatment is particularly challenging, especially where primary data from waste operators are not available.

Engagement with selected stakeholders was very useful in understanding the challenges faced by companies from specific sectors to comply with EU regulatory limitations on legacy substances.

The **input provided by stakeholders** in this Case Study highlights a complex end-of-life chain for this product group, driven by the current technological limitations in waste management operations (relying largely on particularly visual inspection and sorting), that are largely performed in third countries to reduce costs. The absence of end-of-waste criteria for textiles further contributes to the uncertainty regarding the chemical composition of second life textile.

Moreover, customer limitations to the presence of these legacy substances, in products, even these products fully complied with regulatory requirements, were indicated to contribute to the weakening of circularity of products within EU. Therefore, thanks to the information gathered from stakeholders, the need to properly map the waste flows and related chemical content has been clarified in the method, encompassing the presence of regulatory and customer limitations that affect the circularity of products.

6.2 Testing of Section B: Method for developing information requirements for substances of concern

This section aims to test the setting information requirements on substances of concern in the Base Case and along the life cycle, as defined under Art. 2(27) a, b, c and d of ESPR. In particular, the identification of SoCs under Art. 2(27) a, b and c was performed, followed by SoCs under Art. 2(27) d. Finally, the setting of information requirements on SoCs under Art. 2(27) a, b, c, and d was investigated.

Substances of concern under Art. 2(27) (a), (b), (c)

SoCs under Art. 2(27) a, b and c can be univocally identified by their definitions in the ESPR text. These SoCs are reported in **Table 42, Note:** the 'usual name, trade name, abbreviation' for simplicity were not reported in this Case Study.

Table 43 and **Note:** the 'usual name, trade name, abbreviation' for simplicity were not reported in this Case Study.

Table 44 for substances identified in the Base Case. Substances that are present along the life cycle (for simplicity only substances not already listed in **Table 42** are reported) and substances in the recyclate, respectively.

- SoCs under Art. 2(27) a were identified consulting the list of Substances of Very High Concern (SVHC) in the Candidate List for REACH Authorisation (https://echa.europa.eu/en/candidate-list-table).
- For SoCs under Art. 2(27) b, Annex VI of the CLP regulation was cross-checked for the hazard classes of relevant substances, according to the SoC b definition in ESPR. In particular, at the time of writing this document, the Adaptation to Technical Progress (ATP)[419] 18 was used.
- For SoCs under Art. 2(27) c, Annexes I to IV to the Persistent Organic Pollutants (POPs) Regulation[420] were consulted.

Information on specific substances not falling into one of the categories above, but where listing in any of the relevant categories may be under consideration in legislation under development, was flagged in the tables referred to below. This information may be relevant in subsequent development of the delegated act.

Table 42. Identification of SoCs a, b, c (both functional substances and non-intentionally added substances) identified for the Base Case.

Substances	IUPAC; EC; CAS	SoC a, b, c (Art. 2(27) ESPR) * only CLP Harmonized classification (Hazard classes and categories) covered by SoCb definition under ESPR
(benzothiazol-2-ylthio)methyl thiocyanate; TCMTB	IUPAC: 1,3-benzothiazol-2-ylsulfanylmethyl thiocyanate EC: 244-445-0 CAS: 21564-17-0	SoC b (Skin Sens. 1, Aquatic Chronic 1)

419 https://echa.europa.eu/documents/10162/17218/annex_vi_clp_table_atp18_en.xlsx/818d0c3a-5b67-1741-8d4c-eb58d05bb068?t=1666008680907&download=true.

420 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32019R1021.

Substances	IUPAC; EC; CAS	SoC a, b, c (Art. 2(27) ESPR) * only CLP Harmonized classification (Hazard classes and categories) covered by SoCb definition under ESPR
Sodium hypochlorite	IUPAC: sodium;hypochlorite EC: 231-668-3 CAS: 7681-52-9	SoC b (Aquatic Chronic 1)
Polyamide based resin with epichlorohydrin (proxy with epichlorohydrin)	IUPAC: 1-Chloro-2,3-epoxypropane EC: 203-439-8 CAS: 106-89-8	SoC b (Carc. 1B, Skin Sens. 1)
Titanium dioxide	IUPAC: dioxotitanium EC: 236-675-5 CAS: 13463-67-7	SoC b (Carc. 2)
Nonyl phenol ethoxylates (NPEOs)	IUPAC: 2-(2-nonylphenoxy)ethanol EC: 500-024-6 CAS: 9016-45-9	SoC a (Endocrine disrupting properties (Article 57(f) - environment) 4-nonylphenol ethoxylates are not classified according to Annex VI of Regulation (EC) No 1272/2008 (CLP Regulation). In addition, the degradation product 4-nonylphenol is a substance of very high concern included in the Candidate List because of its probable serious effects to the environment as a result of its endocrine disrupting properties, which give rise to an equivalent level of concern[421]
Naphthalene	IUPAC: Naphthalene EC: 214-552-7 CAS: 91-20-3	SoC b (Carc. 2, Aquatic Chronic 1)
1,2,4 – trichlorobenzene	IUPAC: 1,2,4-trichlorobenzene EC: 204-428-0 CAS: 120-82-1	SoC b (Aquatic Chronic 1)
Antimony trioxide	IUPAC: Antimony(III) oxide EC: 215-175-0 CAS: 1309-64-4	SoC b (Carc. 2)
N,N-dimethylacetamide	IUPAC: N,N-dimethylacetamide EC: 204-826-4 CAS: 127-19-5	SoC a, SoC b (Repr. 1B)
Copper	IUPAC: Copper	SoC b

421 ECHA, Support document for identification of 4-nonylphenol, branched and linear, ethoxylated as substances of very high concern because, due to their degradation to substances of very high concern (4-nonylphenol, branched and linear) with endocrine disrupting properties, they cause probable serious effects to the environment which give rise to an equivalent level of concern to those of CMR2 and PBT/vPvB3 substances, Substance Name: 4-Nonylphenol, branched and linear, ethoxylated, 2013, https://echa.europa.eu/documents/10162/9af34d5f-cd2f-4e63-859c-529bb39da7ae.

Substances	IUPAC; EC; CAS	SoC a, b, c (Art. 2(27) ESPR) * only CLP Harmonized classification (Hazard classes and categories) covered by SoCb definition under ESPR
	EC: 231-159-6 CAS: 7440-50-8	(Aquatic Chronic 2)[422]
Pentadecafluorooctanoic Acid (PFOA)	IUPAC: 2,2,3,3,4,4,5,5,6,6,7,7,8,8,8-pentadecafluorooctanoic acid EC: 206-397-9 CAS: 335-67-1	SoC a (Toxic for reproduction (Article 57c) and PBT (Article 57d)) SoC b (Carc.2, Repr. 1B, STOT RE 1) SoC c (listed under the Stockholm Convention[423] and listed under the POPs Regulation[424])

Source: JRC's own elaboration.

Note: the 'usual name, trade name, abbreviation' for simplicity were not reported in this Case Study.

Table 43. Identification of SoCs a, b, c along the life cycle (for simplicity, only substances not already listed in **Table 42**).

Substances	Life cycle stage of emission	IUPAC; EC; CAS	SoC a, b, c (Art. 2(27) ESPR)
Diazinon	Raw material and pre-processing stage (agricultural phase) Manufacturing stage (scouring)	IUPAC: Diazinon EC: 206-373-8 CAS: 333-41-5	SoC b (Aquatic Chronic 1)
Chlropyrifos	Raw material and pre-processing stage (agricultural phase) Manufacturing stage (scouring)	IUPAC: diethoxy-sulfanylidene-(3,5,6-trichloropyridin-2-yl)oxy-λ5-phosphane EC: 220-864-4 CAS: 2921-88-2	SoC b (Aquatic Chronic 1)
Carbon disulphide	Raw material and pre-processing stage (viscose fibres production) Manufacturing stage (scouring)	IUPAC: Carbon disulphide EC: 200-843-6 CAS: 75-15-0	SoC b (Repr. 2, STOT RE 1)
Zinc sulphate	Raw material and pre-processing stage (viscose fibres production) Manufacturing stage (scouring)	IUPAC: Zinc sulphate EC: 231-793-3 CAS: 7733-02-0	SoC b (Aquatic Chronic 1)
Imidazole	Manufacturing stage (scouring, washing)	IUPAC: 1H-imidazole EC: 206-019-2 CAS: 288-32-4	SoC b (Repr. 1B)

[422] This classification is applied to granulated copper; [particle length: from 0,9 mm to 6,0 mm; particle width: from 0,494 to 0,949 mm].
[423] Council Decision (EU) 2015/633 of 20 April 2015 on the submission, on behalf of the European Union, of a proposal for the listing of additional chemicals in Annex A to the Stockholm Convention on Persistent Organic Pollutants, OJ L 104, 23.4.2015, p. 14–15.
[424] Commission Delegated Regulation (EU) 2020/784 of 8 April 2020 amending Annex I to Regulation (EU) 2019/1021 of the European Parliament and of the Council as regards the listing of perfluorooctanoic acid (PFOA), its salts and PFOA-related compounds, OJ L 188I, 15.6.2020, p. 1–3.

Substances	Life cycle stage of emission	IUPAC; EC; CAS	SoC a, b, c (Art. 2(27) ESPR)
Formaldehyde	Manufacturing stage (finishing)	IUPAC: Formaldehyde EC: 200-001-8 CAS: 50-00-0	SoC b (Carc. 1B, Muta. 2, Skin Sens. 1)
Methanol	Manufacturing stage (finishing)	IUPAC: methanol EC: 200-659-6 CAS: 67-56-1	SoC b (STOT SE 1)
Carbon monoxide[425]	End of life (incineration)	IUPAC: carbon monoxide EC: 211-128-3 CAS: 630-08-0	SoC b (Repr. 1A. STOT RE 1)

Source: JRC's own elaboration.

Note: the 'usual name, trade name, abbreviation' for simplicity were not reported in this Case Study.

Table 44. Identification of SoCs a, b, c in the recyclate (first and second case).

Chemicals	IUPAC; EC; CAS	Process from previous life cycle	SoC a, b, c (Art. 2(27) ESPR)
Titanium dioxide	IUPAC: dioxotitanium EC: 236-675-5 CAS: 13463-67-7	Manufacturing (raw material)	SoC b (Carc. 2)[426]
Nonylphenol ethoxylates (NPEOs)	IUPAC: 2-(2-nonylphenoxy)ethanol EC: 500-024-6 CAS: 9016-45-9	Manufacturing (scouring, spinning, knitting, dyeing) End of life (collection and sorting)	SoC a (Endocrine disrupting properties (Article 57(f) - environment)
Naphthalene	IUPAC: Naphthalene EC: 214-552-7 CAS: 91-20-3	Manufacturing (spinning, knitting, dyeing)	SoC b (Carc. 2, Aquatic Chronic 1)
1,2,4 – trichlorobenzene	IUPAC: 1,2,4-Trichlorobenzene EC: 204-428-0 CAS: 120-82-1	Manufacturing (dyeing)	SoC b (Aquatic Chronic 1)
Antimony trioxide	IUPAC: Antimony(III) oxide EC: 215-175-0 CAS: 1309-64-4	Manufacturing (raw material)	SoC b (Carc. 2)

[425] The emission is reported by a research (Ying et al., 2022) conducted at a full-scale MSWI plant in Jiangsu, Province of Southeastern China.

[426] This classification applies to titanium dioxide; [in powder form containing 1 % or more of particles with aerodynamic diameter ≤ 10 μm]. It is reasonable to assume that titanium dioxide present in the recyclate will no longer meet this definition and therefore would not be classified.

Chemicals	IUPAC; EC; CAS	Process from previous life cycle	SoC a, b, c (Art. 2(27) ESPR)
N,N-dimethylacetamide	IUPAC: N,N-dimethylacetamide EC: 204-826-4 CAS: 127-19-5	Manufacturing (raw material)	SoC a (Repr. 1B)
Copper	IUPAC: Copper EC: 231-159-6 CAS: 7440-50-8	Manufacturing (dyeing)	SoC b (Aquatic Chronic 2)[427]

Source: JRC's own elaboration.

Note: the 'usual name, trade name, abbreviation' for simplicity were not reported in this Case Study.

Substances under Art. 2(27) (d)

The identification of SoCs under Art. 2(27) (d) was conducted considering:

- Existing **regulatory limitations** on the placing on the market or use of substances (legislation in force or in preparation); as well as **customer**[428]**-driven limitations** along the supply chain.
- **Technical constraints**, interfering with the processes related to re-use, preparing for reuse or recycling; or with the functionality, usefulness and value of the resulting recycled materials or products for reuse (as specified in Article 5(14)).

Literature sources were consulted for the identification of SoC d for technical constraints and for the identification of the **alert concentration (c_{alert})**, i.e. the concentration indicated by recycling companies, that would lead to disposing of the waste via incineration or landfill rather than more recuperative EoL treatment. The **c_{alert}** level indicates the point at which it is not feasible to manage and reduce the concentration of the substance with pre-treatments prior to sending it to recycling processes located downstream in the process chain. However, for the Case Study, no information from recycling companies was available, hence values for c_{alert} are proposed based on other approaches (e.g. the limit of detection or from current certification schemes) as examples.

Three substances are highlighted as SoC d for existing regulatory limitations to the placing on the market or use of substances; as well as customer-driven limitations. NPEOs, in particular, were indicated by stakeholders as a one of the current major concerns of textile recycling companies. Further information on this evidence, which was collected in the field is reported in the method document **Life cycle stages**. The results of this assessment are reported in **Table 45**, where the rationale for the proposal of the c_{alert} is reported in the column 'Description of the constraints (existing regulatory and customer-driven limitations, technical constraint)'**.**

Substances subject to limitation related to customer requirements (as emissions values or as concentrations in products), according to the main standards and certification schemes for textile products, are flagged in **Table 46.**

[427] This classification is applied to granulated copper; [particle length: from 0,9 mm to 6,0 mm; particle width: from 0,494 to 0,949 mm].

[428] Customer is intended here as the entity purchasing reused or recycled materials (recyclates).

Table 45. Identification of possible SoC d (existing regulatory and technical constraints).

Substance	CAS no.	Substance family	Origin/function	Materials	Functional chemical/ NIAS	Life-cycle stage in which it is used	Description of the constraints (existing regulatory and customer-driven limitations, technical constraint)	C_{alert}
Nonyl phenol ethoxylates (NPEOs)	9016-45-9	Phenol compound	Surfactants, mineral oils	all	NIAS in the final product and in the recycIate	Manufacturing, end of life	Existing regulatory and customer-driven limitations: In restriction for textile articles under REACH (2016)[429]. Moreover, stakeholders reported that customers do not accept compliance with exemption to the REACH restriction.	0.01 % by weight (corresponding to the regulatory threshold)
Pentadecafluorooctanoic Acid (PFOA)	335-67-1	Organofluorine compounds	Water repellent	all	NIAS	Manufacturing	Existing regulatory limitation: Listed under the Stockholm Convention[430] and listed under the POPs Regulation[431]	0.025 mg/kg (corresponding to the regulatory threshold)
N,N-dimethylacetamide	127-19-5	Acetamide compound	Solvent	acrylic	NIAS	Manufacturing	Existing regulatory limitation: Regulation 2018/1513 (carcinogenic, mutagenic or toxic for reproduction (CMR), category 1A or 1B), Entry 72	3000 mg/kg (= 0.3%) (corresponding to the regulatory threshold)
Cyclic trimers of PET .e.g. Ethylene Terephthalate Cyclic Trimer	7441-32-9	By-products of PET polymerisation	Raw materials of PET	PET, recycled PET, acrylic	NIAS	Manufacturing	Technical constraint (quality/process disturbing): Major problems associated with oligomer deposits in textile processing are: visual problems (cloudy appearance) at dark shades and lower brilliancy of shade due to deposition the surface of the fibre; efficiency decrease and more frequent cleaning of the dyeing apparatus due to precipitation on the dyeing apparatus; deposits on the	*Rather than a threshold value,* **any content level** *of trimers appear to affect the dyeing process, indeed a reduction of the content of 22.56% (from about 2%) improved several properties (Li et al., 2021)[434].* *Full removal of the content is not feasible (Montero et*

[429] REACH, ANNEX XVII, Entry 46a, Nonylphenol ethoxylates (NPE), https://echa.europa.eu/documents/10162/7dcd73a4-e80d-47c5-ba0a-a5f4361bf4b1#:~:text=Shall%20not%20be%20placed%20on%20the%20market%20after,or%20of%20each%20part%20of%20the%20textile%20article.

[430] Council Decision (EU) 2015/633 of 20 April 2015 on the submission, on behalf of the European Union, of a proposal for the listing of additional chemicals in Annex A to the Stockholm Convention on Persistent Organic Pollutants, OJ L 104, 23.4.2015, p. 14–15.

[431] Commission Delegated Regulation (EU) 2020/784 of 8 April 2020 amending Annex I to Regulation (EU) 2019/1021 of the European Parliament and of the Council as regards the listing of perfluorooctanoic acid (PFOA), its salts and PFOA-related compounds, OJ L 188I, 15.6.2020, p. 1–3.

[434] Li et al., 2021 Li, H.; Pei, L.; Zhang, H.; Wang, Z.; Saleem, M.A.; Alebeid, O.K.; Wang, J. Extraction of Cyclic Oligomer and Their Influence on Polyester Dyeing in a Silicone Waterless Dyeing System. Polymers 2021, 13, 3687. https://doi.org/10.3390/polym13213687.

Substance	CAS no.	Substance family	Origin/function	Materials	Functional chemical/ NIAS	Life-cycle stage in which it is used	Description of the constraints (existing regulatory and customer-driven limitations, technical constraint)	C_{alert}
							guide rollers of the yarn winding apparatus; dusting on air-jet looms; and more frequent cleaning of production units (Eren and Anis, 2009[432]) "These oligomers can adversely affect the processing of recycled PET, such as dye precipitation on fabric and increased yarn friction." (Bingnan et al., 2023)[433]	*al., 2003)[435]. Tentative limits of detection (LOD) ranging from **0.3 µg/kg to 2 µg/kg** are cited from literature[436]*
/	/	Volatile organic compounds (VOCs)	Degradation product of PET due to wear and recycling	recycled PET	NIAS	/	<u>Technical constraint for thermo-mechanical recycling (quality/process disturbing)</u>: "These can diffuse through the melt and hinder processing, reduce output properties, or even corrode processing equipment" (Duhoux et al., 2021[437])	*A specific value for concentrations hindering recycling was not found. However, the limit for Benzaldehyde (see* **Table 47***) may be considered.* Note: Benzaldehyde is considered as representative NIAS of VOCs in the recycled-PET, but the described effect on machinery may be related also to air emissions of VOCs, that may originate from different source.

432 Eren, H. K. and Anis, P., Surface Trimer Removal of Polyester Fibers by Ozone Treatment, Textile Research Journal Vol 79(7): 652–656 DOI: 10.1177/0040517508097521 https://journals.sagepub.com/doi/epdf/10.1177/0040517508097521.

433 Bingnan Mu, Yuanyi Shao, Lauren McBride, Hannah Hidalgo, Yiqi Yang, Rapid fiber-to-fiber recycling of poly (ethylene terephthalate) and its dye from waste textiles without damaging their chemical structures, Resources, Conservation and Recycling,Volume 197,2023,107102,ISSN 0921-3449,https://doi.org/10.

435 Gerardo Montero, David Hinks, Jacob Hooker, Reducing problems of cyclic trimer deposits in supercritical carbon dioxide polyester dyeing machinery, The Journal of Supercritical Fluids, Volume 26, Issue 1, 2003,https://doi.org/10.1016/S0896-8446(02)00187-0.

436 Emmanouil D. Tsochatzis, Joao Alberto Lopes, Oliver Kappenstein, Thomas Tietz, Eddo J. Hoekstra, Quantification of PET cyclic and linear oligomers in teabags by a validated LC-MS method – In silico toxicity assessment and consumer's exposure, Food Chemistry, 2020, https://doi.org/10.1016/j.foodchem.2020.126427.

437 Duhoux, T., Maes, E., Hirschnitz-Garbers, M., Peeters, K., Asscherickx, L., Maarten Christis, M., Stubbe, B., Colignon, P., Hinzmann, M., Sachdeva, A., Study on the technical, regulatory, economic and environmental effectiveness of textile fibres recycling, Final report, 2021, 10.2873/828412.

Substance	CAS no.	Substance family	Origin/function	Materials	Functional chemical/ NIAS	Life-cycle stage in which it is used	Description of the constraints (existing regulatory and customer-driven limitations, technical constraint)	C_{alert}
Hydrogen peroxide	7722-84-1	Peroxides	Bleaching - oxidative treatment	Cashmere, wool, cotton	Auxiliary - not in the final product	Bleaching	Technical constraint (quality disturbing): "The uncontrolled decomposition of hydrogen peroxide gives rise to OH* radicals. These radicals attack the cellulose fibre starting with oxidation of the hydroxyl groups and eventually ending with the cleavage of the cellulose molecules, decreasing the degree of polymerisation. [...] In order to inhibit these reactions, bleach stabilisers, containing sequestering agents, are usually applied." (BREF for textiles, 2023[438])	An example of a desizing-bleaching padding recipe for PVA/starch blends is for hydrogen peroxide at **0.2-0.4 %** of the bleaching solution (BREF for textiles) *(not as concentration in final product).*

Source: JRC's own elaboration.

Table 46. Identification of customer-driven supply chain limitations for substances in the Base Case and related limits to substances.

Substances	CAS	EU Ecolabel[439]	Blue Angel v. 3 (2023)	Nordic Swan Ecolabel v. 5.5 • 01 March 2022 – 31 December 2026	Restricted Substance List (RSL) (AFIRM Group) v. 09 (2024)	OEKO-TEX 100 Ed. 02.2024	ZDHC Manufacturing Restricted Substance List (MRSL) v. 3.1 (2024)
Disperse Blue 35	12222-75-2	X (Potentially sensitising dyes shall not be used, the limit is zero)	X (50 mg/kg for the end product)		X (15 ppm as reporting limit, 30 ppm for limit in component	X (50 mg/kg at the level of component)	X (250 mg/kg as formulation limit[440])

[438] Joze Roth, Benoit Zerger, Damien De Geeter, Jorge Gómez Benavides, Serge Roudier, Best Available Techniques (BAT) Reference Document for the Textiles Industry, Publications Office of the European Union, Luxembourg, 2023, doi:10.2760/355887, JRC 131874.
[439] COMMISSION DECISION of 5 June 2014 establishing the ecological criteria for the award of the EU Ecolabel for textile products (OJ L 174/45).
[440] ZDHC Manufacturing Restricted Substances List (ZDHC MRSL) V3.1 Aug 2024. The formulation limit are concentration limits for the substances in commercial chemical formulations available from chemical manufacturers.

Substances	CAS	EU Ecolabel[439]	Blue Angel v. 3 (2023)	Nordic Swan Ecolabel v. 5.5 • 01 March 2022 – 31 December 2026	Restricted Substance List (RSL) (AFIRM Group) v. 09 (2024)	OEKO-TEX 100 Ed. 02.2024	ZDHC Manufacturing Restricted Substance List (MRSL) v. 3.1 (2024)
					material in finished product)		
Decabromodiphenyl ethane (DBDPE)	84852-53-9				X (5 ppm as reporting limit, 10 ppm limit in component material in finished product)		
Titanium dioxide	13463-67-7						X (1% (w/w) as formulation limit of TiO2 particles have aerodynamic diameter ≤10 µm)
Nonyl phenol ethoxylates (NPEOs)	9016-45-9	X (25 mg/kg as total sum of specific phenol-based auxiliaries for the final product)	X (100 mg/kg for alkylphenols and alkylphenol ethoxylates combined for the end product, except from recycled materials)	X (100 mg/kg for alkylphenols and alkylphenol ethoxylates combined for the end product)	X (20 ppm as reporting limit total of NPEOs + OPEOs, 100 ppm as limit for APs + APEOs in component material in finished product)	X (50 mg/kg at the level of component)	X (250 mg/kg as formulation limit)
Naphthalene	91-20-3				X (0.2 ppm as reporting limit)	X (2 mg/kg at the level of component)	X (200 mg/kg as formulation limit)
1,2,4 – trichlorobenzene	120-82-1	X (Halogenated dyeing accelerants (carriers) shall not be used, the limit is zero)			X (0.2 ppm as reporting limit, 1 ppm as limit in component	Listed in the expanded requirements in OEKO-TEX 100 standard (1 mg/kg at the level of the component)	

Substances	CAS	EU Ecolabel[439]	Blue Angel v. 3 (2023)	Nordic Swan Ecolabel v. 5.5 • 01 March 2022 – 31 December 2026	Restricted Substance List (RSL) (AFIRM Group) v. 09 (2024)	OEKO-TEX 100 Ed. 02.2024	ZDHC Manufacturing Restricted Substance List (MRSL) v. 3.1 (2024)
					material in finished product)		
Antimony trioxide	1309-64-4	X (as antimony) (30 mg/kg for the end product)			X (as antimony) (3 ppm extractable as reporting limit, 30 ppm extractable as limit in component material in finished product)	X (as antimony) (30 mg/kg at the level of component)	
N,N-dimethylacetamide	127-19-5	X (0,001 % w/w for babies and children under 3 years old and 0,005 % w/w in direct contact and limited contact with the skin, for end product with specific materials)	X (0.1% by mass of the end product)	X (0.1% by mass for specific recycled fibres)	X (50 ppm as reporting limit, 100 ppm limits Component Materials in Finished Product)	X (500 mg/kg, 1000 mg/kg for specific materials, both limits at the level of component)	Included in the Research List of the ZDHC Group (ZDHC, 2014)[441]
Polytetrafluoroethylene (PTFE) (Considering the definition given in Annex XV – Proposal for PFAS restriction, PTFE can be included in PFAS category)	9002-84-0			CAS not present As PFAS: Fillings, stuffing materials, and padding shall not be added and treated, the limit is zero)	CAS not present (As PFAS: 50 ppm as reporting limit as total organic fluoride content)	CAS not present (As PFAS:no intentional use of PFAS, the limit is zero)	

[441] ZERO DISCHARGE OF HAZARDOUS CHEMICALS PROGRAMME (ZDHC). Research List, 2014, https://cdn.prod.website-files.com/5c4065f2d6b53e08a1b03de7/5db6ef17bd2f00c462b11f2b_ResearchList.pdf.

Substances	CAS	EU Ecolabel[439]	Blue Angel v. 3 (2023)	Nordic Swan Ecolabel v. 5.5 • 01 March 2022 – 31 December 2026	Restricted Substance List (RSL) (AFIRM Group) v. 09 (2024)	OEKO-TEX 100 Ed. 02.2024	ZDHC Manufacturing Restricted Substance List (MRSL) v. 3.1 (2024)
Copper	7440-50-8	X (25 mg/kg as limit that applies to products for children)	X (25 mg/kg extractable as limit that applies to end products)	X (250 ppm as limit for the dye according to ETAD for metal impurities in dyes and pigments)	X (5 ppm extractable as reporting limit, 50 ppm extractable for adults and 25 ppm extractable for children, both limits Component Materials in Finished Product)	X (50 mg/kg extractable for adults and 25 mg/kg extractable for children, both limits at the level of component)	X (250 mg/kg as formulation limit for the dye)

Source: JRC's own elaboration.

Information requirements for SoC under Art. 2(27)

This section tests the approach towards defining thresholds to enable the tracking of SoCs in textiles and along their life cycle. In **Table 47** the SoCs in the product are addressed.

It is assumed that no additional substances are added in the use and end of life stage (note: NPEOs are considered being present in the product and then (re)appearing again after sorting).

Due to space limitation and to improve the readability, the required information on substances under Art. 7(5) points b and c of ESPR., is not repeated in this section (see previous sections, i.e. location and maximum concentration).

With respect to information on substances under Art. 7(5) point (d) (i.e. instructions for safe use), as a general principle, the SoCs (and specifically SoC (a) and SoC (b)) should be addressed in order to help to prevent exposure of humans and the environment to these substances under foreseeable conditions of product use and EoL management. This should be performed taking into account the hazard profile of substances, as reported in **Table 47**.

In this Case Study on textiles, an example of "safe use" could relate to SoCs classified as Endocrine disruptors (ED) for the environment (e.g. NPEOs). In this example, suitable management of these SoCs includes avoiding excessive washing during the use phase could be recommended in order to prevent their release from the matrix and any associated environmental exposure. Similarly, regarding information on substances under Art. 7(5) point e, if PS team assesses the presence of a certain SoC (in the example, NPEOs) in the post-consumer waste that could pose risks for workers or to the environment during the EoL operations/ processes, this information may enable waste operators to adopt appropriate preventive / minimisation measures, such as minimise wet treatments, in order to reduce the leakage of substances into wastewater. It should be noted that this information will generally only be useful to operators at an "aggregated level", associated for instance to a particular batch or type of waste (e.g. for instance wool waste). Scientific evidence shows that wastewater treatments may degrade substances in more hazardous metabolites (e.g. nonylphenol (NP) from NPEOs) (Hong et al., 2020)[442] that are ultimately released into the environment. Thus mechanical, dry treatments should be preferred in case such substances are present.

One substance may fall into one or more SoCs categories, for example where a substance is identified as SoC a, b or c according to Art. 2(27) (potentially in several categories simultaneously) and as SoC d (where the substance is restricted in products or assessed as hindering re-use and recycling of the product for technical reasons). Where these simultaneous Art. 2(27) SoC (a), (b), (c), (d) categorisations occur, the generic approach and the substance-specific approach should be applied (the specific approach depending on availability of regulatory thresholds and alert concentrations for SoC (d)).

In this Case Study, which focuses on textile apparel characterised by a largely multinational supply chain with manufacture centred in third countries, it is proposed for SoC (b) to refer to the cut-off values in Table 1.5.1. of GHS, rather than to the thresholds in Table 1.1 of Annex II to REACH. The reason for this is that it is unlikely that chemical mixtures used in third countries will be compliant with the requirements for SDS established under REACH.

Regarding this Case Study specific apparel example, it should be noted that the threshold values suggested for substances classified as skin sensitizers (under CLP) do not take into account the REACH restriction proposal aiming to restrict skin sensitisers in textiles (ongoing at the time of

[442] Hong, Y., Feng, C., Yan, Z. et al. Nonylphenol occurrence, distribution, toxicity and analytical methods in freshwater. Environ Chem Lett 18, 2095–2106 (2020). https://doi.org/10.1007/s10311-020-01060-3.

writing: June 2025). Further information can be found in the ECHA opinion[443] supporting this specific work.

Regarding the point mentioned above on the possibility of overlaps, for the same substance, between thresholds applicable with regard to SoCs (a), (b), (c) and (d), according to the ESPR SoC methodology, **the strictest applicable threshold should apply.** In doing so, the PS team should:

- determine the generic thresholds applicable, according to potential identification as SoC a, b or c. The list of SoCs listed in **Table 47** does not aim to be exhaustive. The tracking applies to all SoCs (a), (b) and (c). The obligation to declare SoCs (a), (b) and (c) is on the manufacturer and it is not constrained by their identification within the Preparatory Study;
- subsequently, to the extent feasible, use evidence gathered from stakeholders (specifically on limitations that are customer-driven and regulatory);
- where information is backed up by literature and other relevant sources, this should also be considered and cross-checked with the previous bullet point, where relevant.

Whenever more than one customer-driven limitation is available, the strictest is considered, in line with the approach stated above. Where a customer-driven limitation excludes/ prohibits the use of a certain substance, the **limit of detection (LOD)** was used as the threshold for tracking the substance (where this is available).

SoCs along the life cycle, according to the method, may, as appropriate, be included as information in the DPP, depending on the nature and potential impact of such emissions. Such an assessment can be considered for future developments on a case-by-case basis. The latter are listed in **Note:** the 'usual name, trade name, abbreviation' for simplicity were not reported in this Case Study.

Table 43.

As currently proposed in the ESPR SoC method, **exemptions** to information requirements may be set with due justification. In addition, **a tiered approach could be proposed for the dates of entry into application of the information requirements** according to the categories of substances, for instance:

- non-intentionally added substances (second [later] tier of priority for information requirement);
- process chemicals not present in the product (considering that, however, the latter are not part of the minimum information as under Art.7(5)) (third tier for information requirements [further postponed, and possibly subject to prior review] .

Further possible substance-specific exemptions, group exemptions or potential proposals for a delayed entry into application of information requirements are not proposed in this illustrative Case Study, since such considerations are highly dependent on the outcome of stakeholder consultation during the Preparatory Study and, as applicable, to the subsequent impact assessment.

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443 https://echa.europa.eu/documents/10162/16dbaec6-4563-6820-ec3d-c0f2124ce725.

Table 47. Example of definition of thresholds for tracking of SoCs a, b, c, d (both functional chemicals and NIAS) in the product.

Substances	IUPAC; EC; CAS	SoC a, b*, c, d (Art. 2(27) ESPR) * only CLP Harmonized classification (Hazard class) covered by SoC b definition under ESPR	Threshold concentration for information requirements (w/w% product, if not otherwise specified)*	Approach
(benzothiazol-2-ylthio)methyl thiocyanate; TCMTB	IUPAC: 1,3-benzothiazol-2-ylsulfanylmethyl thiocyanate EC: 244-445-0 CAS: 21564-17-0	SoC b (Skin Sens. 1, Aquatic Chronic 1)	≥ 0.1 %	Generic approach, concentration limit according to Table 1.5.1 of GHS (Skin sensitization hazard class is the strictest)
Sodium hypochlorite	IUPAC: sodium;hypochlorite EC: 231-668-3 CAS: 7681-52-9	SoC b (Aquatic Chronic 1)	≥ 1 %	Generic approach, concentration limit according to Table 1.5.1 of GHS (Hazardous to the aquatic environment hazard class)
Polyamide based resin with epichlorohydrin (proxy with epichlorohydrin)	IUPAC: 1-Chloro-2,3-epoxypropane EC: 203-439-8 CAS: 106-89-8	SoC b[444] (Carc. 1B, Skin Sens. 1)	≥ 0.1 %	Generic approach, concentration limit according to Table 1.5.1 of GHS (Skin sensitization hazard class is the strictest)
Titanium dioxide	IUPAC: dioxotitanium EC: 236-675-5 CAS: 13463-67-7	SoC b (Carc. 2) SoC d (customer-driven limitation)	≥ 0.1 %	Generic approach, concentration limit according to Table 1.5.1 of GHS (Carcinogenicity hazard class). The proposed approach is stricter than the limit according to the customer-driven limitation (formulation limit = 1 % w/w)[445] . The relevance of setting an information requirement for this substance present in textile products could be further assessed in the Preparatory Study in light of the wording of the specific entry in Annex VI of CLP, which reads

[444] Note: given the impossibility to identify a specific substance with CAS number for "Polyamide based resin with epichlorohydrin", the hazard profile of the most hazardous component has been considered (see Box 6 for more details).

[445] ZDHC Manufacturing Restricted Substances List (ZDHC MRSL) V3.1 Aug 2024. The formulation limit, i.e. concentration limits for the substances in commercial chemical formulations available from chemical manufacturers, are referred to the product in this Case Study.

Substances	IUPAC; EC; CAS	SoC a, b*, c, d (Art. 2(27) ESPR) * only CLP Harmonized classification (Hazard class) covered by SoC b definition under ESPR	Threshold concentration for information requirements (w/w% product, if not otherwise specified)*	Approach
				"titanium dioxide; [in powder form containing 1 % or more of particles with aerodynamic diameter ≤ 10 μm]".
Nonyl phenol ethoxylates (NPEOs)	IUPAC: 2-(2-nonylphenoxy)ethanol EC: 500-024-6 CAS: 9016-45-9	SoC a (Endocrine disrupting properties (Article 57(f) - environment) SoC d (regulatory limitation and customer-driven limitation)	(1) Regulatory limitation: ≥ 0.01 % (2) Customer-driven limitation: ≥ 20 ppm (0.002 %) for component material in finished product	(1) Substance-specific approach, concentration limit below the restriction for textile articles under REACH (2021)[446] and (2) customer-driven limitation according to AFIRM (reporting limit total of NPEOs + OPEOs equal to 20 ppm). The proposed approach is stricter than the limit according to Art. 33(1) REACH (0.1%)
Naphthalene	IUPAC: Naphthalene EC: 214-552-7 CAS: 91-20-3	SoC b (Carc. 2, Aquatic Chronic 1) SoC d (customer-driven limitation)	(1) GHS: ≥ 0.1% (2) Customer-driven limitation: ≥ 0.00002% (for component material in finished products)	(1) Generic approach, concentration limit according to Table 1.5.1 of GHS (0.1% for Carcinogenicity hazard class) (2) Substance specific approach, in line with customer-driven limitation[447] (AFIRM RSL, reporting limit for component material in finished products = 0.2 ppm)
1,2,4 – trichlorobenzene	IUPAC: 1,2,4-trichlorobenzene EC: 204-428-0 CAS: 120-82-1	SoC b (Aquatic Chronic 1) SoC d (customer-driven limitation)	(1) GHS: ≥ 1% (2) Customer-driven limitation: ≥ LOD = 0.009 mg/kg (=9e-7%)	(1) Generic approach, concentration limit according to Table 1.5.1 of GHS (Hazardous to the aquatic environment hazard class). (2) Substance specific approach with the LOD from literature may be considered[448], in line with customer-driven limitation (EU Ecolabel: "Halogenated dyeing accelerants (carriers) shall not be used")

[446] REACH, ANNEX XVII, Entry 46a, Nonylphenol ethoxylates (NPE), https://echa.europa.eu/documents/10162/7dcd73a4-e80d-47c5-ba0a-a5f4361bf4b1#:~:text=Shall%20not%20be%20placed%20on%20the%20market%20after,or%20of%20each%20part%20of%20the%20textile%20article.

[447] AFIRM Restricted Substances List 2024 proposes stricter values as reporting limit for Naphthalene compared to OEKO TEX (2 mg/kg) and ZDHC MRLS (200 mg/kg as formulation limit).

[448] Lu, Y., Zhu, Y. 2013. Determination of chlorobenzenes in textiles by pressurized hot water extraction followed by vortex-assisted liquid–liquid microextraction and gas chromatography–mass spectrometry,
Journal of Chromatography A, https://doi.org/10.1016/j.chroma.2013.10.050.

Substances	IUPAC; EC; CAS	SoC a, b*, c, d (Art. 2(27) ESPR) * only CLP Harmonized classification (Hazard class) covered by SoC b definition under ESPR	Threshold concentration for information requirements (w/w% product, if not otherwise specified)*	Approach
Antimony trioxide	IUPAC: Antimony(III) oxide EC: 215-175-0 CAS: 1309-64-4	SoC b (Carc. 2) SoC d (customer-driven limitation)	(1) GHS: ≥ 0.1% (2) Customer-driven limitation: ≥ 0.0003% (for component material in finished products for antimony)	(1) Generic approach, concentration limit according to Table 1.5.1 of GHS (Carcinogenicity hazard class). (2) Substance specific approach, in line with customer-driven limitation[449] (AFIRM RSL, reporting limit for component material in finished products = 3 ppm extractable)
N,N-dimethylacetamide	IUPAC: N,N-dimethylacetamide EC: 204-826-4 CAS: 127-19-5	SoC a (Repr. 1B), SoC b (Repr. 1B) SoC d (regulatory and customer-driven limitation)	(1) REACH and GHS: ≥ 0.1% (2) Customer-driven limitation: ≥ 50 ppm (0.005%) at the level of the component material	(1) Generic approach, concentration limit according to Article 33(1) of REACH and to Table 1.5.1 of GHS (Reproductive toxicity hazard class). (2) Substance specific approach, in line with customer-driven limitation[450] (AFIRM RSL, reporting limit as solvent residuals for component material in finished products = 50 ppm) The existing regulatory threshold for textile articles is higher compared to the two options (≥ 3000 mg/kg (= 0.3%))[451]
Copper	IUPAC: Copper EC: 231-159-6 CAS: 7440-50-8	SoC b (Aquatic Chronic 2)[452] SoC d (customer-driven limitation)	GHS: ≥ 1 % Customer-driven limitations: ≥ 0.0005% (for component material in finished products)	Generic approach, concentration limit according to Table 1.5.1 of GHS (Hazardous to the aquatic environment hazard class).

[449] AFIRM Restricted Substances List 2024 proposes stricter values as reporting limit for Antimony compared to EU Ecolabel (260 mg/kg for polyester fibres and 30 mg/kg for products for babies), OEKO TEX (30 mg/kg for products for babies) and ZDHC MRLS (50 mg/kg and 250 mg/kg as formulation limit for dyes and pigments, respectively).

[450] AFIRM Restricted Substances List 2024 proposes stricter values as reporting limit for Antimony compared to EU Ecolabel (260 mg/kg for polyester fibres and 30 mg/kg for products for babies), OEKO TEX (30 mg/kg for products for babies) and ZDHC MRLS (50 mg/kg and 250 mg/kg as formulation limit for dyes and pigments, respectively).

[451] COMMISSION REGULATION (EU) 2018/1513 of 10 October 2018 amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards certain substances classified as carcinogenic, mutagenic or toxic for reproduction (CMR), category 1A or 1B.

[452] This classification is applied to granulated copper; [particle length: from 0,9 mm to 6,0 mm; particle width: from 0,494 to 0,949 mm].

Substances	IUPAC; EC; CAS	SoC a, b*, c, d (Art. 2(27) ESPR) * only CLP Harmonized classification (Hazard class) covered by SoC b definition under ESPR	Threshold concentration for information requirements (w/w% product, if not otherwise specified)*	Approach
				Substance specific approach, in line with customer-driven limitation[453] (AFIRM RSL, reporting limit for component material in finished products = 5 ppm extractable)
Pentadecafluorooctanoic Acid (PFOA)	IUPAC: 2,2,3,3,4,4,5,5,6,6,7,7,8,8,8-pentadecafluorooctanoic acid EC: 206-397-9 CAS: 335-67-1	SoC a (Toxic for reproduction (Article 57c)#PBT (Article 57d)) SoC b (Carc.2, Repr. 1B, STOT RE 1) SoC c (listed under the Stockholm Convention[454] and listed under the POPs Regulation[455]) SoC d (regulatory limitation)	≥ 0.0000025 %	Substance-specific approach, concentration limit below the restriction under the POPs Regulation[456] The proposed threshold is stricter than the generic approach, with concentration limit according to Art. 33(1) REACH, to Table 1.5.1 of GHS (Carcinogenicity and Reproductive toxicity hazard classes).
Cyclic trimers of PET .e.g. Ethylene Terephthalate	IUPAC: 3,6,13,16,23,26-hexaoxatetracyclo[26.2.2.28,11.218,21]hexatriaconta-1(31),8,10,18(34),19,21(33),28(32),29,35-nonaene-2,7,12,17,22,27-hexone CAS:: 7441-32-9	SoC d (Technical constraint (quality/process disturbing)	0.3 μg/kg to 2 μg/kg	Substance-specific approach, tentative limit of *detections (LOD) available from literature*[457] *may be considered*

453 AFIRM Restricted Substances List 2024 proposes stricter values as reporting limit for Copper compared to EU Ecolabel (25 mg/kg for products for babies), OEKO TEX (30 mg/kg for products for babies and 50 mg/kg for adults) and ZDHC MRLS (50 mg/kg and 250 mg/kg as formulation limit for dyes and pigments, respectively).

454 Council Decision (EU) 2015/633 of 20 April 2015 on the submission, on behalf of the European Union, of a proposal for the listing of additional chemicals in Annex A to the Stockholm Convention on Persistent Organic Pollutants, OJ L 104, 23.4.2015, p. 14–15.

455 Commission Delegated Regulation (EU) 2020/784 of 8 April 2020 amending Annex I to Regulation (EU) 2019/1021 of the European Parliament and of the Council as regards the listing of perfluorooctanoic acid (PFOA), its salts and PFOA-related compounds, OJ L 188I, 15.6.2020, p. 1–3.

456 Commission Delegated Regulation (EU) 2020/784 of 8 April 2020 amending Annex I to Regulation (EU) 2019/1021 of the European Parliament and of the Council as regards the listing of perfluorooctanoic acid (PFOA), its salts and PFOA-related compounds, OJ L 188I, 15.6.2020, p. 1–3.

457 Emmanouil D. Tsochatzis, Joao Alberto Lopes, Oliver Kappenstein, Thomas Tietz, Eddo J. Hoekstra, Quantification of PET cyclic and linear oligomers in teabags by a validated LC-MS method – In silico toxicity assessment and consumer's exposure, Food Chemistry, 2020, https://doi.org/10.1016/j.foodchem.2020.126427.

Substances	IUPAC; EC; CAS	SoC a, b*, c, d (Art. 2(27) ESPR) * only CLP Harmonized classification (Hazard class) covered by SoC b definition under ESPR	Threshold concentration for information requirements (w/w% product, if not otherwise specified)*	Approach
Benzaldehyde (as Volatile organic compounds (VOCs)	IUPAC: Benzaldehyde EC: 202-860-4 CAS: 100-52-7	SoC d (Technical constraint (quality/process disturbing) and possible future SoCa	≥ 0.1% or 1% w/w (depending on the class of mutagenicity) - this threshold is suggested to be further assessed with future regulatory developments (included any possible derogation)	Considering that this substance is in the Community rolling action plan (CoRAP) as Suspected Mutagenic CLP, a threshold under the generic approach equal to Table 1.5.1 GHS could be set.
Disperse Blue 35	IUPAC: 1,5-diamino-4,8-dihydroxy-2-(4-hydroxyphenyl)anthracene-9,10-dione EC: 602-260-6 CAS: 12222-75-2	SoC d (customer-driven limitation)	≥ LOD (20 mg/Kg)	Substance-specific approach, based on the EU Ecolabel (sensitising dyes shall not be used)
Decabromodiphenyl ethane (DBDPE)	IUPAC: 1,1'-(Ethane-1,2-diyl)bis(pentabromobenzene) EC: 284-366-9 CAS: 84852-53-9	SoC d (customer-driven limitation)	≥ 5 ppm (i.e. 0.0005% w/w)	Substance-specific approach, based on the reporting limit set in Restricted Substance List (RSL) (AFIRM Group) v. 09 (2024)[458]
Polytetrafluoroethylene (PTFE)	IUPAC: Ethene, 1,1,2,2-tetrafluoro-, homopolymer EC: 618-337-2 CAS: 9002-84-0	SoC d (customer-driven limitation)	≥ LOD = 13 μg F g^{-1}	Substance-specific approach, based on the Nordic Swan Ecolabel and OEKO TEX standard (no addition/intentional use of PFAS). The LOD from literature[459] may be considered.

Source: JRC's own elaboration.

Note: the 'usual name, trade name, abbreviation' for simplicity were not reported in this Case Study.
* According to the methodology, the level of granularity of the thresholds for information requirements needs to be established case-by-case according to the type of product, also considering the feasibility and proportionality. In the present case study, the concentration is calculated also at components level, when appropriate, for the scope of testing of the workability of the methodology.

458 https://afirm-group.com/wp-content/uploads/2024/04/2024_AFIRM_RSL_2024_0404_EN.pdf.
459 Skedung, L., Savvidou, E., Schellenberger, S., Reimann, A., Cousins, I., T., Benskin, J. P., 2024, Environmental Science: Processes & Impacts, http://dx.doi.org/10.1039/D3EM00438D.

Box 9. Comments and lessons learnt from testing of Section B: Method for developing information requirements for substances of concern.

One challenge encountered was the use of some limits reported in **certification schemes** to identify potential customer-driven limitations to substances **(SoC (d) for customer-driven limitations**). Some of these customer-driven limitations referred to **formulation limits** (i.e. concentration limits for the substances in commercial chemical formulations available from chemical manufacturers), e.g., ZDHC for titanium dioxide. In order to overcome this issue, the same **approach** was followed as performed for the identification of SoC (b) (Table 1.1 of Annex II REACH (substances in mixtures)). That is, the threshold concentration is set in relation to the **product weight (w/w)**, unless there are other case-by-case considerations. In addition, where a customer-driven limitation excludes/ prohibits the use of a certain substance, the **approach** followed to define the threshold for tracking the substance relied on the **limit of detection (LOD)** (where this is available).

The Case Study identified little information on **SoC (d) for technical constraints,** given the paucity of information found in literature, and noting that in this illustrative example, no stakeholder consultation was able to be undertaken (usually, the prime source of such information).

It was not possible to clearly establish the precise origin and disrupting mechanism(s) for all suspected SoCs (d). Textile products literature information sources often referred to ***families of substances*** (e.g. VOCs), instead of to the specific chemicals being used. In this case, the **approach** followed was to assume one specific **representative substance** for the family of substances, e.g., Benzaldehyde (as indicated for food packaging), The **form of the substance** is also relevant (e.g., the titanium dioxide reported example), when identifying the necessary threshold concentration for reporting information requirements. In the example of titanium dioxide, its form as used in the production of viscose fibres could be taken into account during the Preparatory Study, when potentially setting an information requirement, with regard to the wording of the specific entry (in this case) in Annex VI of CLP, which reads “titanium dioxide; [in powder form containing 1 % or more of particles with aerodynamic diameter ≤ 10 μm]”.

6.3 Testing of Section C: Method for developing performance requirements on substances

The initial step to develop performance requirements for substances requires the investigation of any possible relationship between the use or the presence of one or several substances, and one or several of the 16 product aspects listed in Article 5(1) of ESPR. This could be complemented using the product parameters included in Annex I of ESPR. A method for the assessment of the relevant circularity aspects within a product group is outlined in the separate ESPR report on Task B2 (Method for the assessment of circularity aspects and integration in or relation with the Method for the Ecodesign of Energy-related Products (MEErP)), which can be used as a reference. However, for simplification in this Case Study, the BREF document and other relevant sources on apparel textiles were used instead. A discussion of relevant product aspects is reported in the following subsections. The product aspects to be analysed were chosen considering the information available from data sources.

In this Case Study, in order to simplify the analysis, the effect of substances on some product aspects such as ((a) durability, (g) the presence of SoCs, (h) energy use and energy efficiency, (i) water use and water efficiency, (j) resource use and resource efficiency, (p) expected generation of waste) is done based mainly on information from the BREF for textiles and other literature sources. Potential thresholds for product parameters (Annex I, ESPR) were identified for the product aspects mentioned above, depending on data availability. Moreover, when mentioned in the BREF, alternative substances are reported to be potentially considered for further investigation.

For the product aspect (o) environmental impacts, including carbon footprint and environmental footprint, a simplified life cycle assessment was conducted, and preliminary results were obtained. A potential hotspot was identified and its contribution to the impact categories was compared with several references. The references for potential subsequent tiers of performance requirements were identified according to data/information contained in the BREF document.

The analysis of alternatives (testing of Section C2) was performed with regards to the alternatives identified for the product aspect (o) only, since in this case specific amounts of potential alternative substances to the identified hotspot were available in the BREF.

Product aspect (a) “durability” and (p) “expected generation of waste”

Durability and expected generation of waste may be linked for different reasons, thus these aspects are analysed together following some insights from literature research including the PS on textiles 2nd milestone.

Cyclic trimers of polyethylene terephthalate (PET) such as ethylene terephthalate cyclic trimers (CAS 7441-32-9) are possible impurities in polyester (PES) fibres that may cause major problems associated with oligomer deposits in textile processing. These problems could be visual problems (cloudy appearance) at dark shades and lower brilliancy of shade due to deposition on the surface of the fibre (Eren and Anis, 2009)[460]. It is thus assumed that the presence of cyclic trimers may induce both the manufacturer and the customer to dispose of the fabric and product prematurely, affecting indirectly the generation of waste and the durability of the product, respectively. Thus, the generation of waste considered in this section refers to both the manufacturing and use stages of the product.

Under ESPR, durability is intended as ‘physical durability’. However, the ‘emotional durability’, defined as ‘the product’s relevance and desirability to a user, or multiple users, over time’ (Ellen MacArthur Foundation, 2021)[461], can also be taken into account in Task 4 ‘Consumer behaviour’ of

[460] Eren, H. K. and Anis, P., Surface Trimer Removal of Polyester Fibers by Ozone Treatment, Textile Research Journal Vol 79(7): 652–656 DOI: 10.1177/0040517508097521 https://journals.sagepub.com/doi/epdf/10.1177/0040517508097521.

[461] Ellen MacArthur Foundation. 2021. Circular business models: redefining growth for a thriving fashion industry.

the MEErP. Moreover, compromised aesthetic features may affect the quality and, consequently, the durability of the product.

The proposed <u>maximum threshold</u> can be defined consistently with the c_{alert} (**Table 45**), i.e. considering the limit of detection (LOD) ranging from 0.3 μg/kg to 2 μg/kg available from literature[462].

The concentration of cyclic trimers of PET as calculated in the Base Case (c_{BC}) (**Table 28**) is 3% with respect to polyester, recycled PET and nylon and (cumulatively) 0.57% with respect to the product, thus this substance could potentially be considered for performance requirements.

Moreover, sodium hypochlorite (CAS 7681-52-9), that may be used in bleaching process, is addressed in BREF as problematic for different reasons, not only related to durability:

- For wool treatment, fibres can be discoloured and damaged, thus hydrogen peroxide is used. Dichloroisocyanurate is indicated as more advantageous alternative to sodium hypochlorite because it has the ability to release chlorine gradually, thereby reducing the risk of fibre damage;
- Bleaching with sodium hypochlorite leads to secondary reactions that form organic halogen compounds, commonly quantified as AOX and for ecological reasons now its use is limited in Europe. However, it should be noted that in general chlorine and chlorine-releasing compounds, including sodium dichloroisocyanurate, are capable of reacting with organic compounds to form AOX.

For the reasons reported above, the use of sodium hypochlorite is reported in the BREF for textiles as being limited to a small number of installations. Since less aggressive agents on fibres are available (e.g. Dichloroisocyanurate), the preliminary suggestion would be to further assess the ban of sodium hypochlorite and substitution with Dichloroisocyanurate.

However, given the qualitative nature of available information, further investigations would be needed before proposing sodium hypochlorite as a candidate substance for possible performance requirements, to properly understand the conditions of use for the installations that still employ sodium hypochlorite and to then collect data to define a maximum threshold or potential substitution with alternative substances. Therefore, sodium hypochlorite is not proposed at present, based on the data available, to be investigated further for a possible performance requirement (in the context of this Case Study).

Product aspect (h) "energy use and energy efficiency", (i) "water use and water efficiency", (p) "expected generation of waste" and (j) resource use and resource efficiency

These product aspects are here investigated as a group since, according to the BREF for textiles, they are linked for specific substances. Product aspect (p) "expected generation of waste" is therefore analysed again for the specific substances discussed in this section.

The use of reactive dyes (considered in the present Case Study for the dyeing process of wool, cashmere and acrylic fibres), affects several product aspects. According to the BREF for textiles "when dyeing with reactive dyes, two rinsing steps at about 80 °C are normally carried out after dyeing, in order to remove the unfixed dye. This leads to higher consumption of water (approximately 30% more [270, CRAB 2001]) and energy." (BREF for textiles, page 693).

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Due to the poor fixation rate of this family of dyes, significant water discharges arise, compared to other families of dyes. Indeed, for reactive dyes, the percentage of non-fixed dye that may be discharged in the effluent may be up to 60% (BREF for textiles, Table 2.16).

Alternative dyes may be considered for wool, cashmere and acrylic fibres, for example acid dyes, whose upper limit for percentage of non-fixed dye is 20%. This value may be proposed as the maximum value of the product parameter *(r) amounts of waste generated, including plastic waste and packaging waste and their ease of reuse, and amounts of hazardous waste generated* (Annex I, ESPR)**.** The generation of waste considered in this section refers to the manufacturing stage of the product.

Acid dyes show lower ranges of unfixed dye (5-20%), thus reducing the generation of waste (i.e. non-fixed dye in wastewater). Moreover, acid dyes are compatible with wool fibres. Thus, the preliminary suggestion would be to consider the ban of (certain) reactive dyes and promoting their substitution with acid dyes, due to their impact on the product aspect (p) "expected generation of waste". Elements of proportionality and whether the main motivation for considering a restriction would be primarily chemical safety, would have to be taken into consideration before formulating any proposal.

However, further investigations with stakeholders would be needed to properly estimate the correspondent savings in water, energy and resource consumption achievable with different families of dyes, while ensuring compatibility with the considered type of fibres. Therefore, reactive dyes are not proposed to be investigated further for a possible performance requirement (in the context of this Case Study).

Product aspect (m) "recyclability"

Volatile organic compounds (VOCs) are reported in this Case Study as process disturbing for thermo-mechanical recycling. The recycling process referred to in this Case Study is mechanical treatment, which is not characterised by the melting process of polymers; however, VOCs are flagged since it may be relevant to further consider any possible negative effect of the presence of VOCs during mechanical recycling.

Benzaldehyde is considered as representative of VOCs. It could be potentially present in recycled-PET. However, air emissions of VOCs may also originate from other different sources may provoke negative effects on recycling. Given the qualitative and incomplete information, further investigation and discussions with stakeholders would be needed to properly identify a maximum threshold of VOCs along the apparel textile value chain. Therefore, benzaldehyde is not proposed to be investigated further for a possible performance requirement (in the context of this Case Study).

Product aspect (o) "environmental impacts, including carbon footprint and environmental footprint"

For the purpose of this Case Study, a simplified LCA was performed, where the life cycle of the Base Case was modelled in SimaPro 9.6[463] and EF 3.1[464] reference packages and the results were used to identify reference values and limit values to substances.

The aim of this LCA was not to provide a full and comprehensive analysis as required in the PEF, but to identify the hotspots in terms of substances for the subsequent steps of the Task B5 method. For this reason, some steps as required in the PEF (e.g. full Life Cycle Impact Assessment with characterised, normalised and weighted results for each EF impact category and as a single overall score and Data quality and uncertainty assessment) are not reported in this document.

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463 SimaPro v. 9.6, 2024 PRé Sustainability B.V. https://pre-sustainability.com/solutions/tools/simapro/.

464 European Commission, European Platform on LCA (EPLCA), https://eplca.jrc.ec.europa.eu/LCDN/developerEF.html.

Goal and scope

The scope of the LCA is to assess the environmental impact of the Base Case consisting in a representative product for the sub-category "sweaters and midlayers", and to investigate the hotspots in terms of substances along the life cycle of the Base Case and potential alternative substances, as basis for further investigations when considering setting performance requirements related to product aspect (o) as indicated by Art. 5(1) of ESPR.

Functional unit and reference flow

The functional unit defines the qualitative and quantitative aspects of the function(s) and/or service(s) provided by the product being evaluated. The functional unit definition answers the questions:

- The function(s)/service(s) provided ("what"): garment to keep the upper body warm and covered;
- The extent of the function or service ("how much"): one 'sweater and midlayer';
- The expected level of quality ("how well"): wear in good condition with appropriate use (depending on the durability and consumer behaviour – aspects not further investigated in this assessment);
- The duration/lifetime of the product ("how long"): 85 wears.

System boundaries

The study follows a cradle-to-grave approach, so the system boundaries encompass: the supply-chain of the raw materials used for the manufacturing of the sweater and midlayer (fibres, intentionally and not intentionally added substances, process auxiliaries not remaining in the product), all the steps required for the manufacturing of the sweater and midlayer (fibres production, yarn production, fabric production, dyeing, finishing), the distribution to the consumer, the use of the sweater and midlayer, and its final disposal at the end of its service life. **Figure 13** represents the lifecycle stages considered.

Environmental Footprint impact categories

The impact categories of the EF3.1 method (Andreasi Bassi et al., 2023)[465] were considered, which includes 16 environmental impact categories.

Life cycle inventory

The life cycle stages were modelled based on the data sources mentioned before, for what concerns amount and type of raw materials as in **Table 25**, type of manufacturing processes, distribution and end of life treatments.

The further breakdown regarding substances for the substance-related life cycle inventory was compiled consistently with the quantification of substances reported in **Table 29Table 29.** Input amounts and emissions during manufacturing of the Base Case (aLC) (functional substances and auxiliary substances, i.e. process chemicals, not designed to remain in the product) for the manufacturing stage, Table 38. Emissions from the landfilled fraction of the Base Case to water. and **Table 40.** Concentration at the stack for Base Case incinerated and emissions for substances at the end of life stage, reported in the previous subsections.

465 Andreasi Bassi S., Biganzoli F., Ferrara N., Amadei A., Valente A., Sala S., Ardente F., Updated characterisation and normalisation factors for the Environmental Footprint 3.1 method. Publications Office of the European Union, Luxembourg, 2023, doi:10.2760/798894, JRC130796.

Data for water and energy use in the manufacturing processes and in the use stage were elaborated from the Ecoinvent 3.9.1 database (Wernet et al., 2016)[466].

Additional information on the choice of datasets for the production of substances and availability of characterisation factors for emissions necessary for the impact calculation can be found in **Table 64.**

The main life cycle inventory tables, including the quantification of additional flows (energy and other resources consumption, as well as waste treatment) are reported in **Appendix II – Life cycle inventory tables (Table 65, Table 66, Table 67, Table 68).**

A limitation of the life cycle inventory is the representation of the upstream agricultural phase and the end-of-life stage: the emissions contained in the aggregated EF datasets representing these stages were added to the emissions identified and quantified in the Case Study. Thus, a double-counting of impacts generated by the emissions can occur for these stages. This action was needed to include also other flows of these stages (e.g. resources and energies consumption), that were not in the scope of the Case Study and were not quantified.

Interpretation

Identification of the most-relevant impact categories

Impact categories that together contribute to at least 80% of the single overall score are identified in **Table 48**. The calculation method is Environmental Footprint 3.1 V1.00 / EF 3.1 normalization and weighting set, released with SimaPro EF3.1 database (March 2023). The product analysed is the Base Case.

The functional unit for the calculation is 0.5 kg (corresponding to one 'sweater and midlayer').

466 Wernet, G., Bauer, C., Steubing, B., Reinhard, J., Moreno-Ruiz, E., and Weidema, B., 2016. The ecoinvent database version 3 (part I): overview and methodology. The International Journal of Life Cycle Assessment, [online] 21(9), pp.1218–1230. Available at: http://link.springer.com/10.1007/s11367-016-1087-8.

Table 48. Identification of the most-relevant impact categories (highlighted in yellow).

Impact category	Unit	Total	LCS1 Raw materials acquisition and pre-processing	LCS2 Manufacturing	LCS3 Distribution	LCS4 Use	LCS5 End of life	%	Sum %
Total	Pt	1.12E-02	8.21E-03	2.58E-03	4.79E-05	3.15E-04	1.97E-05	100	
Climate change	Pt	1.91E-03	1.08E-03	7.22E-04	1.32E-05	8.57E-05	7.26E-06	17.12	81.01
Ecotoxicity, freshwater	Pt	1.81E-03	1.03E-03	7.17E-04	1.90E-06	5.58E-05	1.00E-05	16.25	
Particulate matter	Pt	1.36E-03	1.25E-03	9.53E-05	8.36E-06	1.16E-05	-1.08E-07	12.20	
Acidification	Pt	1.22E-03	1.15E-03	5.46E-05	5.07E-06	7.84E-06	-1.20E-08	10.91	
Water use	Pt	1.01E-03	8.85E-04	9.62E-05	7.52E-08	2.47E-05	-1.16E-08	9.01	
Eutrophication, terrestrial	Pt	8.81E-04	8.41E-04	3.25E-05	3.42E-06	4.20E-06	1.53E-07	7.89	
Eutrophication, marine	Pt	8.51E-04	8.23E-04	1.93E-05	2.25E-06	6.65E-06	2.98E-07	7.63	
Resource use, fossils	Pt	6.16E-04	1.64E-04	3.85E-04	8.20E-06	6.12E-05	-2.63E-06	5.51	
Land use	Pt	4.59E-04	4.55E-04	2.33E-06	7.51E-08	2.15E-06	-1.89E-08	4.11	
Ozone depletion	Pt	2.46E-04	1.87E-07	2.46E-04	2.60E-12	3.43E-09	-2.48E-11	2.21	
Eutrophication, freshwater	Pt	2.04E-04	1.93E-04	6.83E-06	1.09E-08	3.75E-06	4.49E-08	1.82	
Resource use, minerals and metals	Pt	1.61E-04	1.10E-04	4.78E-05	1.56E-07	2.86E-06	-1.68E-07	1.44	
Photochemical ozone formation	Pt	1.44E-04	9.37E-05	3.95E-05	4.71E-06	5.32E-06	2.66E-07	1.29	
Human toxicity, non-cancer	Pt	1.39E-04	1.11E-04	2.12E-05	2.63E-07	5.89E-06	5.85E-07	1.25	
Human toxicity, cancer	Pt	1.27E-04	1.81E-05	7.01E-05	1.47E-07	3.47E-05	4.33E-06	1.14	
Ionising radiation	Pt	2.39E-05	2.52E-06	1.84E-05	7.58E-08	3.17E-06	-3.10E-07	0.21	

Source: JRC's own elaboration.

Identification of the most-relevant life cycle stages

All life-cycle stages that together contribute more than 80% to each most relevant impact category (based on the characterised inventory results) are reported in **Table 49**. The calculation method is Environmental Footprint 3.1 V1.00 / EF 3.1 normalization and weighting set, released with SimaPro EF3.1 database (March 2023). The product analysed is the Base Case.

The functional unit for the calculation is 0.5 kg (corresponding to one 'sweater and midlayer').

Table 49. Identification of the most-relevant life cycle stages of the Base Case (highlighted in yellow).

Impact category	LCS1 Raw materials acquisition and pre-processing (%)	LCS2 Manufacturing (%)	LCS3 Distribution (%)	LCS4 Use (%)	LCS5 End of life (%)	Sum %
Climate change	56.67	37.77	0.69	4.48	0.38	94.44
Ecotoxicity, freshwater - part 1	78.98	19.88	0.32	0.34	0.48	98.86
Ecotoxicity, freshwater - part 2	46.45	48.61	0.01	4.35	0.58	95.06
Particulate matter	91.55	6.99	0.61	0.85	-0.01	91.55
Acidification	94.46	4.48	0.42	0.64	0.00	94.46
Water use	87.98	9.56	0.01	2.45	0.00	87.98
Eutrophication, terrestrial	95.43	3.68	0.39	0.48	0.02	95.43
Eutrophication, marine	96.66	2.26	0.26	0.78	0.04	96.66

Source: JRC's own elaboration.

Identification of the most relevant processes

All processes that together contribute (along the entire life cycle) more than 80% to that impact category (based on the characterised inventory results), considering absolute values, are reported in **Table 50**. The calculation method is Environmental Footprint 3.1 V1.00 / EF 3.1 normalisation and weighting set, released with SimaPro EF3.1 database (March 2023). The product analysed is the Base Case.

The functional unit for the calculation is 0.5 kg (corresponding to one 'sweater and midlayer').

Table 50. Identification of the most relevant processes related to substances (highlighted in yellow) in the process contribution of the entire life cycle of the Base Case for the most relevant impact categories. For the details about the fibres concerned by the process, please consult **Figure 13**.

Category	Process	Unit	Total	LCS
Acidification	Wool {GLO} | sheep | production mix, at farm | 1 kg wool | LCI result	%	91.3	1 - Raw materials acquisition and pre-processing
Climate change	Wool {GLO} | sheep | production mix, at farm | 1 kg wool | LCI result	%	51.9	1 - Raw materials acquisition and pre-processing
	Process steam from natural gas {RoW} | technology mix regarding firing and flue gas cleaning | production mix, at heat plant | MJ, 90% efficiency | LCI result	%	15.4	2 - Manufacturing
	Polytetrafluoroethylene (PTFE) {GLO} | suspension polymerisation of tetrafluoroethylene | production mix, at plant | petrochemical based | LCI result	%	12.2	2 - Manufacturing
Ecotoxicity freshwater, pt.1	Wool {GLO} | sheep | production mix, at farm | 1 kg wool | LCI result	%	75.6	1 - Raw materials acquisition and pre-processing
	Scouring (emissions)	%	14.2	2 - Manufacturing
Ecotoxicity freshwater, pt.2	Wool {GLO} | sheep | production mix, at farm | 1 kg wool | LCI result	%	45.2	1 - Raw materials acquisition and pre-processing
	Washing (emissions)	%	31.6	2 - Manufacturing

Category	Process	Unit	Total	LCS
	Bleaching (cotton) (emissions)	%	6.35	2 - Manufacturing
Particulate matter	Wool {GLO} | sheep | production mix, at farm | 1 kg wool | LCI result	%	85	1 - Raw materials acquisition and pre-processing
Eutrophication, terrestrial	Wool {GLO} | sheep | production mix, at farm | 1 kg wool | LCI result	%	92.2	1 - Raw materials acquisition and pre-processing
Eutrophication, marine	Wool {GLO} | sheep | production mix, at farm | 1 kg wool | LCI result	%	91.4	1 - Raw materials acquisition and pre-processing
Water use	Wool {GLO} | sheep | production mix, at farm | 1 kg wool | LCI result	%	59.7	1 - Raw materials acquisition and pre-processing
	Cotton fibre {GLO} | technology mix | production mix, at farm | "as is" delinted product | LCI result	%	28	1 - Raw materials acquisition and pre-processing

Source: JRC's own elaboration.

The first hotspot identified for substances is the production process of PTFE for Climate change, while the other highlighted hotspots regard the toxicity categories and in particular the elementary flows (emissions) occurring in the processes and they are previously discussed**.**

A sensitivity analysis for the selection of the PTFE dataset is previously reported.

Identification of the most relevant elementary flows

The most relevant elementary flows are those that contribute cumulatively to at least 80% of the total impact of a most relevant impact category for each most relevant process. If disaggregated data are available, for each most relevant process, all direct elementary flows contributing cumulatively at least to 80% to that impact category should be considered (caused by the direct elementary flows only).

For simplicity, “Ecotoxicity, freshwater” is analysed. The “Ecotoxicity, freshwater” impact category is highlighted as the most affected by the elementary flows (emissions) for scouring, washing and bleaching processes in the “Manufacturing” stage (**Table 50**). As explained in the method Section C1, it is not possible to identify the elementary flows that contribute the most to the processes, since the toxicity results should not be used for ranking substances or for comparison purposes.

It is important to remember that the emissions from the “Manufacturing” stage were modelled in the present Case Study as the discharge of the undegraded substances according to mass balance calculations for each manufacturing process, consistently with the worst-case scenario assumptions. Thus, the degrading effect of the associated wastewater treatment plant (WWTP) was not considered.

An analogous approach was applied for the emissions occurring in the End-of-Life stage, with two further assumptions on:

— the use phase, where almost all the substances (with the exceptions of NPEOs, melamine-based compounds and substances used in the anti-felt treatment for which data about discharges were found) are assumed not removed from the product during domestic washing, due to lack of data to available to the authors. Thus, the amount of these substances is assumed to be found also on the waste;

— the landfilling, where the composition of the waste is assumed to be identical to that of the leachate, i.e., as leached out. As previously reported, in the present Case Study, the mass leaching out corresponds to the total amount of substance(s), following a worst-case scenario. Where more accurate information is not available, an alternative and less conservative approach to estimating such releases would be the use of the default release rates from ECHA, 2012[467].

Regarding the direct emissions to freshwater considered in the scouring (**Table 29**) and affecting "Ecotoxicity, freshwater" as result of the LCIA step, they are listed here (no ranking is intended by the order in which they are reported below):

— Diazinon (as an impurity remaining on raw wool and cashmere, from pesticides application);

— Chlorpyrifos (as an impurity remaining on raw cotton for pesticides application);

— Zinc sulphate (as impurity remaining on viscose fibres);

— Carbon disulphide (as impurity remaining on viscose fibres);

— Nonylphenol ethoxylates (NPEOs) (due to detergent used in scouring and preparation agent in spinning in fibres);

— Mineral oil (due to preparation agent in spinning in fibres);

— Naphthalene (as impurity present in mineral oil);

— Imidazole (due to preparation agent in spinning in fibres).

Regarding emissions to freshwater considered in the washing process depicted in **Figure 13,** and affecting "Ecotoxicity, freshwater" they are listed here (without performing ranking):

— Nonylphenol ethoxylates (NPEOs) (due to detergent used in washing);

— Mineral oil (due to preparation agent in spinning in yarn and lubricant in knitting);

— Naphthalene (as impurity in mineral oil);

— Imidazole (due to preparation agent in spinning of yarn);

— Ethylenediaminetetraacetic acid (EDTA) (used as complexing agent in washing).

For what concerns the emissions to freshwater considered in the bleaching (cotton) and affecting "Ecotoxicity, freshwater" they are listed here (without performing ranking):

— Sodium hypochlorite;

— Sodium hydroxide;

— Nonylphenol ethoxylates (NPEOs).

Identification of the hotspots for substances

According to the method, the contribution of the production of PTFE is analysed over the entire life cycle of the Base Case considering the single overall score.

With the proposed approach, the process "Polytetrafluoroethylene (PTFE) {GLO} | suspension polymerisation of tetrafluoroethylene | production mix, at plant | petrochemical based | LCI result"

[467] European Chemicals Agency (ECHA), 2012, Guidance on information requirements and chemical safety assessment Chapter R.18: Exposure scenario building and environmental release estimation for the waste life stage, https://echa.europa.eu/documents/10162/17224/r18_v2_final_en.pdf/e2d1b339-f7ca-4dba-8bdc-76e25b1c668c.

contributes to the single score for **4.96 %**. This result could be considered for further assessments in a broader context, where also the results of the contribution of the other flows – not related to substances, are evaluated and discussed with stakeholders, particularly with regards to the identification of alternatives. A summary of the evaluation about possible performance requirements on PTFE production is previously reported.

Concerning toxicity categories, the procedure reported in the method is followed, i.e. the substances contributing to the characterised results are reported along with their origin, and substances strictly correlated to the life cycle of the Base Case are flagged to the attention of authorities. By way of example, the results for Ecotoxicity freshwater pt. 1 (total result is 1.7E3 CTUe (Comparative Toxic Unit for aquatic ecotoxicity impacts)) are reported in **Table 51**, highlighting the contribution of the life cycle stages.

Table 51. Substances contributing to Ecotoxicity freshwater pt. 1 results for the Base Case in the whole life cycle.

Contributing substances	Emission compartment	Percentage contribution (%) on LCS1 – Raw material acquisition and pre-processing	Percentage contribution (%) on LCS2 – Manufacturing	Percentage contribution (%) on LCS3 – Distribution	Percentage contribution (%) on LCS4 – Use	Percentage contribution (%) on LCS5 – End of life
Total		**78.98**	**19.88**	**0.32**	**0.34**	**0.48**
Chlorpyrifos	Water	93.74	6.26	0	0	0
Bifenthrin	Water	99.98	0.02	0	0	0
Diazinon	Water	0	100	0	0	0
Chloride	Water	50.43	43.77	3.86	2.05	-0.11
Chlorpyrifos	Soil	99.99	0.01	<0.01	<0.01	<0.01
Bifenthrin	Air	99.98	0.02	0	0	0
Ammonia	Air	98.59	1.21	<0.01	0.18	<0.01
Chlorpyrifos	Air	99.98	0.02	<0.01	<0.01	<0.01
Cypermethrin	Water	99.99	0.01	<0.01	<0.01	<0.01
Bifenthrin	Soil	99.98	0.02	<0.01	<0.01	<0.01
Diazinon	Soil	100	<0.01	0	<0.01	0
Acetic acid	Water	0.51	99.49	<0.01	<0.01	<0.01
Benzene, 1,2,4-trichloro-	Water	0	36.96	0	0	63.04
Ammonium, ion	Water	54.46	27.23	0.01	11.47	6.83
Ammonia, NL	Air	100	<0.01	0	<0.01	0
Cadmium (II)	Soil	99.02	0.28	0.01	0.70	-0.01
Chromium, ion	Water	16.65	82.81	0.19	0.35	<0.01

Contributing substances	Emission compartment	Percentage contribution (%) on LCS1 – Raw material acquisition and pre-processing	Percentage contribution (%) on LCS2 – Manufacturing	Percentage contribution (%) on LCS3 – Distribution	Percentage contribution (%) on LCS4 – Use	Percentage contribution (%) on LCS5 – End of life
Cyanide	Water	0.71	99.14	<0.01	0.14	<0.01
Deltamethrin	Water	99.51	0.42	0.05	0.02	<0.01
Aclonifen	Water	99.94	0.06	0	0	0
Acetochlor	Water	100	<0.01	<0.01	<0.01	<0.01
Cadmium (II)	Water	55.36	36.55	3.96	4.15	-0.02
Cypermethrin	Air	99.98	0.02	<0.01	<0.01	<0.01
Ammonia	Water	2.32	68.28	0.01	29.41	-0.02
Benzene, 1,2-dichloro-	Water	6.55	93.45	<0.01	<0.01	<0.01
Carbon disulfide	Water	0.02	99.98	<0.01	<0.01	<0.01
Diuron	Soil	100	<0.01	<0.01	<0.01	<0.01
Aclonifen	Soil	99.94	0.06	0	<0.01	0

Source: JRC's own elaboration.

A synthetic discussion of the results in **Table 51** is reported below, analysing the origin of the substances. The production of wool from sheep is responsible for the emission of **Chlorpyrifos** to water, air and soil, **Bifenthrin** to water, air and soil, **Ammonia** to air, **Cypermethrin** to water and air, **Diazinon** to soil, **Ammonia, NL**[468] to air**, Deltamethrin** to water, **Aclonifen** in water and soil, **Acetochlor** to water and **Diuron** to soil. Regarding the emissions listed above, it should be noted that chlorpyrifos has been listed as a POP in the Annex I of the Stockholm Convention in May 2025[469].

Emissions of **Diazinon** to water occur during scouring (manufacturing stage), considering the fibres as depicted in **Figure 13*,*** as remaining carryover pesticide impurity (assumed undegraded). **Chloride** emissions in water occurs mainly in the sodium bicarbonate production process (manufacturing stage), in the production of wool from sheep and in the production of cotton. Emission of **Acetic acid** to water occur in the finishing process, anti-felt treatment of wool (manufacturing stage). Emission of **Benzene, 1,2,4-trichloro-** to water occurs at the landfilling of the waste (end of life stage) and in the dyeing process (manufacturing stage). Emission of **Ammonium, ion** in water occurs mainly in the production of acrylic fibres (raw material supply stage). Emission of **Cadmium (II)** to soil occurs mainly in the production of wool (including all the inputs and outputs of breeding sheep during the agricultural phase) and cotton. Emission of **Chromium, ion** in water is due mainly to the energy consumption in the dyeing process (manufacturing stage). **Cyanide** in water is emitted mainly in the production of EDTA used in the manufacturing stage. Emission of **Cadmium (II)** in water occurs mainly in the production of wool

468 This flow refers to the regionalized emission of Ammonia in the Netherlands.

469 See Decision SC-12/9 "Listing of chlorpyrifos" in the advance document containing decisions adopted in COP 12 of the Stockholm Convention. https://www.pops.int/TheConvention/ConferenceoftheParties/Meetings/COP12/tabid/9744/Default.aspx.

(agricultural phase) and cotton and in the energy consumption in the dyeing process (manufacturing stage). Emission of **Ammonia** to water occurs mainly in the reactive dyeing process (manufacturing stage). Emission of **Benzene, 1,2-dichloro-** to water occurs mainly in the production process of the direct dyes used in the manufacturing stage. Emission of **Carbon disulphide** to water occurs in the production process of cotton.

The summary of substances potentially flagged for possible further attention by authorities under other legislation is reported by way of example for the category Ecotoxicity, freshwater pt. 1 in **Table 52.**

Table 52. Substances related to the raw materials supply and pre-processing and manufacturing stages potentially flagged for competent legislations for Ecotoxicity, freshwater pt. 1.

Substance	CAS number	Origin process of emission	Comment
Chlorpyrifos Bifenthrin Cypermethrin Aclonifen Acetochlor Diuron Deltamethrin	2921-88-2 82657-04-3 52315-07-8 74070-46-5 34256-82-1 330-54-1 52918-63-5	Wool production from sheep	Reported in EF dataset (aggregated), thus the origin cannot be defined unambiguously. Probably used as pesticides on sheep wool.
Diazinon	333-41-5	Agricultural stage (raw material supply and pre-processing stage) and scouring (manufacturing stage)	Added in LCI, emission during the application of pesticide to sheep and emission of carry-over pesticide as impurity during scouring (assumed undegraded).
Sodium bicarbonate	144-55-8	Emissions of Chloride, ion during the production of Sodium bicarbonate (that is used in the manufacturing)	Reported in EF dataset (aggregated) as emissions from the sodium bicarbonate production process. Sodium bicarbonate is used in direct dyeing (manufacturing stage) (assumed undegraded).
Ammonia	7664-41-7	Reactive dyeing (manufacturing stage)	Added in LCI, emission in water occurs mainly in the reactive dyeing (manufacturing stage) (assumed undegraded).
Direct Orange 62	12222-38-7	Emissions of Benzene, 1,2-dichloro- in water (CAS 95-50-1) during the production of Direct Orange 62 (that is used in the manufacturing)	Reported in EF dataset (aggregated) as emissions from the Direct Orange 62 production process used in direct dyeing (manufacturing stage)
Carbon disulphide	75-15-0	Cotton production	Reported in EF dataset (aggregated) as emissions from cotton production (manufacturing stage)
Acetic acid	64-19-7	Finishing (anti-felt treatment) (manufacturing stage)	Added in LCI, emission during the finishing process (assumed undegraded).
Benzene, 1, 2, 4, trichloro	120-82-1	Landfilling (End of life stage) and disperse dyeing (manufacturing stage)	Added in LCI, emission during the landfilling of the product and during the dyeing process (assumed undegraded). Recommendation may be given for the manufacturing stage.
EDTA	60-00-04	Emissions of cyanide (CAS 57-12-5) during the production of EDTA (that is used in the manufacturing)	Added in the inventory, for its production emission of Cyanide occur affecting Ecotoxicity, freshwater. Recommendation may be given for the manufacturing stage.

Source: JRC's own elaboration.

Identification of references for the identified hotspot for product aspect (o)

As reported in the previous sections, the aim of this section is to identify reference values and potential limit values for substances identified as hotspots. However, it should be considered that, in general, the LCA results may be subject to variations depending on the inventory data, on the update of the datasets and possible updates of the CFs. Also, it is important to consider the relevance of other flows that are mapped and assessed via LCA and the target substances identified for other product aspects.

In this subsection, an **example of the analysis preparatory** to the potential setting of performance requirements is performed and where possible alternatives to the identified substance "hotspot" (in the example, PTFE) are assessed.[470] It should be highlighted that the identification of PTFE production as a potential hotspot is proposed, and thus further assessments should be made, where also the results of the contribution of the other flows – not related to substances, are evaluated and discussed with stakeholders, particularly with regards to the identification of alternatives (see the summary of the outcome of the analysis).

PTFE is used to give water repellence to clothing articles in finishing. In the BREF for textiles, fluorine-free alternatives are reported. These alternatives are flagged as already in use in the market with reasonable use capacities (BREF for textiles, Table 4.88). Possible issues with substances D4, D5, D6[471] as impurities, relevant to silicone-based alternatives, are also reported in the BREF for textiles. These alternatives are assessed in alternative scenarios of the life cycle of the Base Case, where the formulation for water repellence finishing is reported in **Table 53**, together with the resulting process contribution for the Climate Change category over the product life cycle (excluding the use stage).

A reduction in the process contribution can be observed for Climate Change in the case of both alternatives. However, to avoid burden shifting to other impact categories, or to other aspects such as safety, the potential impacts should all be considered in the comparison. Note that this assessment will be performed in the testing for Section C2. Since the results strongly depend on the chosen dataset, a sensitivity analysis for the selection of the PTFE dataset is previously reported.

Table 53. Possible alternative substances to PTFE and their contribution to Climate change (as input and emissions) on the entire life cycle of the Base Case.

Alternative formulation	Substances (CAS)	EF 3.1 dataset	Input amount to finishing	Water emissions during finishing	Data and sources	Process contribution to Climate change
Silicone-based	Dimethylpolysiloxane (107-51-7)	Polysiloxane {GLO} | Technology mix | Production mix, at plant | LCI result (proxy)	225 g	217 g	These products are generally supplied as aqueous emulsions consisting of polysiloxane-active substances (dimethylpolysiloxane and modified derivatives), emulsifiers, hydrotropic agents (glycols) and water (BREF page 867). No information about the shares of the components	1.15%
	2,6,8-Trimethyl-4-nonyloxypolyethylene oxyethanol (60828-78-6)	Ethoxylated trimethylolpropane triacrylate {GLO} | Technology mix | Production mix, at	12.3 g	*No CF available – not assessed*		0.04%

[470] The assessment in this case study is carried-out without prejudice of the scope and possible outcomes of the "universal restriction on PFAS" currently being assessed by the European Chemicals Agency (ECHA).

[471] ANNEX XVII TO REACH – Conditions of restriction, Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles https://echa.europa.eu/documents/10162/0ac1f453-ad41-4010-e837-a68273b896ca

Alternative formulation	Substances (CAS)	EF 3.1 dataset	Input amount to finishing	Water emissions during finishing	Data and sources	Process contribution to Climate change
		plant | LCI result (proxy)			in the mixture, thus the same composition of the mixture with PTFE is assumed (see **Table 26**). Amounts from Table 4.89 BREF for textiles (data referred to 90 m^2 textiles, average fabric weight per m^2 183.05 g/m^2 [472])	
	Ammonium sulfate (7783-20-2)	Ammonium sulfate, per kg n {GLO} | production mix, at plant | 100% N | LCI result	204.87 g	204.87 g	No specific chemical reported in the BREF for the catalyst for water repellency finishing - assumed the same catalyst used in finishing, easy-care. Assumed to not be retained by the fibres.	1.48%
Wax-based	Paraffin wax (8002-74-2)	Wax production {EU+EFTA+UK} | technology mix | production mix, at plant | 100% active substance | LCI result	102 g	49.4 g as paraffin waxes (petroleum), hydrotreated; 49.4 g as paraffin waxes (petroleum), clay-treated	These formulations consist of ca. 25 % of a paraffin and 5 – 10 % of zirconium, aluminium-based salts (BREF page 866). The remaining share is assumed being water. No specific amount available for this formulation, thus the same amount for silicone-based is assumed. The emission is assumed equally shared among the two available types of CFs for paraffin waxes in EF 3.1.	0.08%
	Aluminium sulfate (7783-24-9)	Aluminium sulphate powder production {EU+EFTA+UK} | technology mix | production mix, at plant | 100% active substance | LCI result	41 g	39.5 g as aluminium sulphate	These formulations consist of ca. 25 % of a paraffin and 5 – 10 % of zirconium, aluminium-based salts (BREF page 866). The remaining share is assumed being water. No specific amount available for this formulation, thus the same amount for silicone-based is assumed.	0.02%

Source: JRC's own elaboration.

Given the improved performance assessed in the process contribution results for Climate change over the life cycle (excluding the use stage), the use of the two possible alternative substances may be considered for finishing (water repellence) to improve the environmental footprint of the Base Case. The results in **Table 54** accounts for the whole impact generated by the input and output flows reported in **Table 53** to treat the Base Case (0.5 kg) with a water repellent agent.

[472] Calculated fabric weight per m^2 as weighted average based on data in https://parcelpath.com/how-much-does-a-sweater-weigh/.

Table 54. Environmental footprint results of the possible alternative substances to PTFE as in **Table 53** – for finishing process with application of water repellent only. In yellow highlight, the results for the hotspot category for PTFE (i.e. Climate change).

Category	Unit	PTFE-based recipe (current)	Reference values from silicone-based recipe	Reference values from wax-based recipe
Acidification	mol H+ eq	4.16E-03	1.14E-02	7.76E-04
Climate change	kg CO2 eq	8.40E+00	1.62E+00	1.06E-01
Ecotoxicity, freshwater - part 1*	CTUe	5.84E+00	3.23E+01	4.76E+02
Ecotoxicity, freshwater - part 2*	CTUe	2.38E+00	1.76E+04	7.73E-02
Particulate matter*	disease inc.	1.06E-07	1.02E-07	7.57E-09
Eutrophication, marine	kg N eq	6.43E-04	1.40E-03	1.26E-04
Eutrophication, freshwater	kg P eq	5.27E-05	8.37E-05	1.52E-05
Eutrophication, terrestrial	mol N eq	7.05E-03	1.47E-02	1.37E-03
Human toxicity, cancer*	CTUh	8.71E-09	7.57E-10	4.56E-11
Human toxicity, non-cancer*	CTUh	1.07E-08	6.26E-04	7.48E-07
Ionising radiation	kBq U-235 eq	1.67E-02	6.56E-02	5.11E-03
Land use	Pt	1.53E+00	3.31E+00	1.87E-01
Ozone depletion	kg CFC11 eq	2.04E-04	2.92E-07	4.11E-10
Photochemical ozone formation	kg NMVOC eq	2.15E-03	4.58E-03	4.50E-04
Resource use, fossils	MJ	1.03E+01	3.04E+01	5.78E+00
Resource use, minerals and metals	kg Sb eq	1.47E-05	3.86E-06	1.23E-06
Water use	m3 depriv.	2.90E-01	1.13E+00	2.56E-02

Source: JRC's own elaboration.

Note: Impact categories marked with * are reported for completeness, but cannot in principle be considered to define performance requirements for substances (given direct link to chemical safety).

The potential limit amount of PTFE-based mixture for water repellence was calculated considering the linearity between LCI and LCIA.

Thus, according to the following proportion, the potential limit input amount of PTFE that reduces impact in Climate change from the current PTFE-based recipe to the reference for a first tier of performance requirement is:

$$LimitPTFE \;=\; \frac{(58.4\ g\ \times 1.62\ kg_{CO2eq})}{8.4\ kg_{CO2eq}} = 11.3\ g$$

Where

$58.4\ g$ is the input amount of PTFE to the current water repellence treatment (a_{LC});

$1.62\ kg_{CO2eq}$ is the characterized result for Climate change of the silicone-based recipe;

$8.4\ kg_{CO2eq}$ is the characterized result for Climate change of the PTFE-based recipe.

The total limit amount of the PTFE-based mixture is then calculated accordingly, considering that PTFE is the 55% of the weight of the mixture and corresponds to 20.5 g.

As already mentioned, the PTFE could be proposed for further investigations, including with stakeholders, in order to further analyse the proposed limit as performance requirement, weighting it with the results obtained in the broader context of a full study, where the product aspects are investigated with regard to all the information gathered. The proposed performance requirement should also be further investigated with regard to its technical feasibility.

According to the Task B5 SoC methodology, where the reduction of PTFE would impair the delivery of the expected functionality (water repellence), the two alternative substances (already identified) should be considered and evaluated (viz. section C2) as possible substitutes, in order to avoid any regrettable substitution. In the present Case Study, it has not been possible to evaluate further the possible performance requirements on PTFE, also in term of its effect on its functionality. However, the evaluation of alternatives is still performed, with the aim of testing the workability of the methodology.

Sensitivity analysis - Use of an alternative dataset for PTFE production

The sensitivity analysis substitutes the dataset used in the current LCI 'Polytetrafluoroethylene (PTFE) {GLO} | suspension polymerisation of tetrafluoroethylene | production mix, at plant | petrochemical based | LCI result' with an alternative available dataset 'Polytetrafluoroethylene (PTFE) granulate {GLO w/o EU+EFTA+UK} | polymerisation of tetrafluorethylene | production mix, at plant | 2.16 g/cm3 | LCI result'.

The choice of the dataset influences the results, as reported in **Table 55**. In the column 'Variation', the applied formula is:

$$Variation = \frac{(ImpactCat._{BCalt} - ImpactCat._{BC})}{ImpactCat._{BC}} \times 100$$

Where:

$ImpactCat._{BCalt}$ is the characterized result for the impact category of the alternative Base Case;

$ImpactCat._{BC}$ is the characterized result for the impact category of the current Base Case.

Table 55. Characterized results of the lifecycle of the Base Case in the current scenario and in the alternative scenario

Impact category	Unit	Base Case life cycle	Base Case life cycle (alternative PTFE dataset)	Variation
Acidification	mol H+ eq	1.09E+00	1.09E+00	0.01%
Climate change	kg CO2 eq	6.86E+01	6.10E+01	-11.04%
Ecotoxicity, freshwater - part 1	CTUe	1.70E+03	1.70E+03	-0.03%
Ecotoxicity, freshwater - part 2	CTUe	3.66E+03	3.66E+03	-0.05%
Particulate matter	disease inc.	9.05E-06	9.33E-06	3.03%
Eutrophication, marine	kg N eq	5.62E-01	5.62E-01	0.02%
Eutrophication, freshwater	kg P eq	1.17E-02	1.16E-02	-0.43%
Eutrophication, terrestrial	mol N eq	4.20E+00	4.20E+00	0.02%
Human toxicity, cancer	CTUh	1.03E-07	9.54E-08	-7.53%
Human toxicity, non-cancer	CTUh	9.75E-07	9.69E-07	-0.66%
Ionising radiation	kBq U-235 eq	2.01E+00	2.01E+00	0.11%
Land use	Pt	4.74E+03	4.74E+03	-0.03%
Ozone depletion	kg CFC11 eq	2.04E-04	2.82E-07	-99.86%
Photochemical ozone formation	kg NMVOC eq	1.23E-01	1.23E-01	0.15%
Resource use, fossils	MJ	4.81E+02	4.85E+02	0.83%
Resource use, minerals and metals	kg Sb eq	1.36E-04	1.48E-04	9.27%
Water use	m3 depriv.	1.36E+02	1.36E+02	-0.02%

Source: JRC's own elaboration.

The categories of Climate change (and Ozone depletion) are those with a significant impact reduction (-11.04% and -99.86% respectively) when moving from the current Base Case to the alternative Base Case. This result can of course change also the process contribution. In fact, under the alternative scenario the process contribution of PTFE production to Climate change in the overall lifecycle is equal to **1.35%**. Under this scenario, **PTFE production would not be considered a most relevant process**.

Summary of results for the assessment of candidate substances towards performance requirements

The substances assessed in the Case Study as potential candidate target substances for performance requirements are reported in **Table 56**, together with the life cycle stage in which they are included/generated and the relevant product aspect under Article 5(1). If the substance is assessed as a potential candidate for performance requirements, the proposed limit in the materials is also reported. Other substances in the Case Study that might affect product aspects are also listed in the table, noting that further investigation would be required before contemplating the possible proposal of a limit threshold.

Table 56. Outcome of the assessments regarding the identification of substances candidate to performance requirements among the potential target substances in the Case Study.

Name	CAS	Function	Life cycle stage	Product aspects	Proposed limit	Comment
Cyclic trimers of polyethylene terephthalate (PET)	7441-32-9	NIAS	Raw material supply	(a) "durability", (p) "expected generation of waste"	LOD= 0.3 µg/kg - 2 µg/kg	The substance is identified as a candidate for a performance requirement according to the proposed limit value. The generation of waste considered in this section refers to both the manufacturing and use stages of the product.
Sodium hypochlorite	7681-52-9	Oxidant agent	Manufacturing, bleaching process	(a) "durability", (p) "expected generation of waste"	n.a.	The substance is not proposed as a candidate for performance requirement due to incomplete and qualitative information. Less aggressive agents on fibres are available (e.g. Dichloroisocyanurate), thus the preliminary suggestion would be to further assess the appropriateness of considering a ban of sodium hypochlorite towards its possible substitution with Dichloroisocyanurate. However, the use of sodium hypochlorite is reported in the BREF for textiles as being limited to a small number of installations. Further investigations are needed to properly understand the conditions of use for the installations that still employ sodium hypochlorite and collect data to define a maximum threshold.
Reactive dyes	/	Colorant	Manufacturing, dyeing process	(h) "energy use and energy efficiency", (i) "water use and water efficiency", (p) "expected generation of waste" and (j) resource use and resource efficiency	n.a.	Thia family of substances is not proposed as a candidate for performance requirement due to incomplete information. The use of reactive dyes is concerning for several interlinked product aspects. Acid dyes show lower range of unfixed dye (5-20%), thus reducing the generation of waste (i.e. non fixed dye in wastewater). Moreover, acid dyes are compatible with wool fibres. Thus, the preliminary suggestion would be to further assess the appropriateness of proposing a restriction on reactive dyes and the substitution with acid dyes, limited to the product aspect (p) "expected generation of waste". However, further investigations would be needed to properly estimate the correspondent savings in water, energy and resource consumption achievable with different families of dyes.
Benzaldehyde	100-52-7	NIAS	Raw material supply	(m) "recyclability"	n.a.	The substance is not proposed as candidate for performance requirement due to incomplete and qualitative information available regarding the process-disturbing behaviour of VOCs. Further investigation and discussions with stakeholders are needed to properly identify a maximum threshold of VOCs along the apparel textile value chain

Name	CAS	Function	Life cycle stage	Product aspects	Proposed limit	Comment
Polytetrafluoroethylene (PTFE)	9002-84-0	Water repellent	Manufacturing, finishing	(o) “environmental impacts, including carbon footprint and environmental footprint”	/	The substance is not proposed as candidate for performance requirement. PTFE results as significant at midpoint level for the Climate change impact category. However, there is the need to consider the contribution of PTFE production to the single overall score (4.96%) in a broader context, where also the results of the contribution of the other flows (not related to substances), are evaluated and discussed with stakeholders, particularly with regards to the identification of alternatives. Moreover, the uncertainty related to the choice of the dataset representing PTFE production should be taken into account.

Source: JRC’s own elaboration.

Note: “n.a.” means “not available” for substances for which further investigations are needed.

Box 10. Comments and lessons learnt from the testing of Section C1: Determining the impact of substances in products on Article 5(1) product aspects.

The testing showed the importance of having **primary data** relevant to the definition of **maximum thresholds** for substances in order to set performance requirements. In particular, feedback should be collected not only from recycling companies but also manufacturers, as regards substances affecting e.g. durability and water and energy use.

Indications about the effect of substances on water and energy use may be provided also via the Environmental Footprint, e.g. with the category water use, in order to aggregate the impact results along the life cycle of the product. However, expert judgment is necessary, or primary data, to get the necessary degree of detail for the life cycle inventory (e.g. the amount of water needed to properly remove process substances from the fabric).

In the Case Study, substance-specific information regarding resources and energy consumption was not available.

As a further development, data about the **abatement efficiency** of the wastewater treatment plants could be considered in a sensitivity analysis, where an alternative scenario with **degraded emissions** would be considered and compared with the current scenario (i.e. emissions are undegraded/unabated).

Specifically regarding the **calculation of the Environmental Footprint**, some reflections are reported hereafter to point out to the practitioners aspects to be taken into account when addressing substances in the inventory.

The quantification of the substances (both as input and emissions) performed in the testing on Section A represented the basis for the life cycle inventory. The EF 3.1 datasets for textile treatments were consulted as a source of data and, as a general outcome, the coverage of substances and the level of details provided in the datasets varied depending on the process, compared to the level of detail found in the BREF for textiles. However, the documentation of the datasets provided useful information regarding the represented technologies and conditions of use.

For example, the 'dyeing batch' process considers a 1% dye shade. The percentage dye shade in textiles represents the relative amount on fibres compared to the total weight. The EF 3.1 dataset may thus represent an **average scenario** (approach generally applied to the LCA). These conditions may differ to those considered in the Case Study, where the **worst-case scenario** is applied, i.e. taking into account the highest possible concentration of dye shade on products, according to literature.

Testing of Section C2: Evaluation of alternatives (preventing regrettable substitution)

Section C2 results from applying the principle that, when considering a substance for performance requirements (as the output of Section C1), the availability of suitable alternative(s) needs to be considered to complement the assessment and to avoid causing any regrettable substitution of substances. In doing this, the functionality and technical/economic feasibility need to be taken into consideration, as well as the safety and sustainability aspects. The outcome of this evaluation will be considered as further evidence to propose, reconsider or abandon any proposed performance requirements for substances.

With specific regard to the current Case Study, according to the results from the Section C1, PTFE (polytetrafluoroethylene), used as finishing agent in the final product, was identified as a potential hotspot for Climate change impact category (product aspect (o)), in particular during its manufacturing process. Accordingly, a specific limit is tentatively proposed towards a performance requirement. In the context of the evaluation of alternatives, PTFE can be then flagged as target substance.

It should be noted that the methodology suggests performing the evaluation of alternatives only where the performance requirement proposes a ban of the target substance, or a threshold that could prevent the delivery of its functionality; this has not been verified for PTFE in this Case Study. Nevertheless, an evaluation is still provided in order to test the workability of the whole methodology. The same exercise could be conducted on cyclic trimers of polyethylene terephthalate (PET), flagged already as potential candidate to performance requirements because of the negative effects on product aspects (a) "durability" and (p) "expected generation of waste" (and SoC (d) for technical constraints, i.e. quality/process disturbing, see **Table 45**). However, the development of section C2 on these substances would imply broader considerations related to the material itself, given that cyclic trimers of polyethylene terephthalate (PET) are impurities due to the raw materials of PET. Thus, for simplicity, PTFE was chosen to test Section C2. The Case Study also limits the evaluation of the alternatives to chemical substitutes. However, it should be highlighted that the Section C2 methodology also suggests investigating alternative technologies and processes.

According to the Section C2 methodology, the available chemical alternatives are first screened from the perspective of the technical-economic feasibility of the substitution (Step 1), then assessed for their safety and sustainability aspects (Step 2); finally, the alternatives are evaluated considering the possible trade-off between the different aspects (Step 3).

Step 1_Identification of alternatives (analysis of functionality, technologies and cost)

The first step of the analysis of alternatives tries to determine whether alternative(s) exist on the market with the same technical function and economic characteristics as the target substance. Both chemical and functional substitutes should be taken into consideration. To achieve this, the approach of the Analysis of Alternatives (AoA) required in the context of AfA (Application for Authorisation) process of REACH has been followed.

In Section C1 of the Case Study, PTFE was identified as a target substance to be considered for a potential performance requirement. PTFE is used across multiple textile products and provides specific functions with regard to chemical inertness (protective clothing), hydrophobicity (protective and outdoor clothing) and water vapour permeability.

In order to screen the alternatives available to substitute PTFE as a water repellent, in the application of textiles finishing, the following sources have been consulted:

1. BREF Textile (JRC)[473]

[473] https://eippcb.jrc.ec.europa.eu/reference/textiles-industry

According to the BREF Textile, in addition to fluorochemicals, the most commonly applied commercial formulations providing water repellence fall under the following categories:

- Wax-based repellents (paraffin -metal salt formulations);
- Resin-based repellents (fatty modified melamine resins);
- Silicone-based repellents

2. REACH Restriction proposal on PFAS (Annex E_Annex XV, ECHA)[474]

According to the PFAS restriction proposal, possible alternatives to fluorochemicals with an ability to provide water repellence include:

- Paraffin-based formulations;
- Polysiloxanes;
- Modified melamine resins;
- Polyurethanes; and
- Dendrimers.

According to the referred restriction proposal on PFAS, alternative technologies relying on spinning and weaving of the textile have also been identified as a chemical-free option for providing water repellence. Such techniques are based on control of the surface roughness and weaving density. One available technology, for example, provides water repellence as a result of fibre swelling when in contact with moisture. The size increase of fibres closes the weave and thereby prevents penetration of the fabric by water, while allowing body vapour to escape.

In the context of the current Case Study, with the purpose of illustrating how to test the method, only two chemical alternatives already on the market and providing a similar functionality to that of the target substance were screened to be further investigated for their safety and sustainability aspects: **silicone-based** and **wax-based.**

<u>Silicone-based</u>
According to the BREF and PFAS restriction proposal, silicone-based repellents are commonly used in the textile industry to give water repellence to fabrics. Polysiloxanes, also known as silicones, are polymers composed of repeating units of siloxane functional groups (e.g., [-O-SiR1R2-]n). Silicones found in a variety of commercial products contain a rigid rough surface patterning that allows them to repel liquids effectively and be used as water repellent agents. Different functional groups, including fluorine-containing ones, may be added to silicones. These finishing agents are generally made of elastomeric polydimethylsiloxanes (PMDS) which can coat the fabric surface after curing. The structure obtained after finishing by padding of the fabric surface is a three-dimensional, flexible and hydrophobic layer bonded to the fabric's fibres.

Example of products available on the market: Vetro Power Fabric & Leather Protection (Vetro Power 2022); protectME Fabric Protector Spray (protectME 2022a); protectME Premium Footwear Protector (protectME 2022b); Nanoman Fabric + Textile Protective Coating (Nanoman 2022).

[474] https://echa.europa.eu/it/restrictions-under-consideration/-/substance-rev/72301/term?_viewsubstances_WAR_echarevsubstanceportlet_SEARCH_CRITERIA_NAME=Per-+and+polyfluoroalkyl+substances+%28PFAS%29&_viewsubstances_WAR_echarevsubstanceportlet_SEARCH_CRITERIA_EC_NUMBER=-

Wax-based

According to the BREF and PFAS restriction proposal, wax-based repellents are also used in the textile industry to give water repellence to fabrics. Paraffin waxes, which are mixtures of hydrocarbons, are white or colourless solids derived from petroleum or oil shale. Paraffins have a general formula of C_nH_{2n+2} and consist of branched (iso), cyclic, straight-chain, and aromatic alkanes. As used in treatments for converted textiles and leathers, this alternative is usually an emulsion of paraffins made up of metal salts (commonly aluminum, zinc, and zirconium) and fatty acids like stearic acid. Paraffin emulsions containing metal ions create asymmetrical macromolecules with a polar head and hydrophobic tail. These molecules self-orient on textile surfaces, with the polar metal salts binding to the textile surface and allowing the hydrophobic hydrocarbon chains to face outwards.

Example of products available on the market: Vectra 16 and 22 (Vectra Enterprises, Inc. 2009); Thompsons Water Seal Fabric Seal (The Thompson's Company 2021); Collonil Carbon Pro (Collonil 2021); Carpet and Fabric Protector (Ultra Chem Labs 2021)

It should be noted that the two alternatives described above were already identified in the context of Section C1. Specifically, the two alternatives were used to build the reference product against which the Base Case (including the target substance) was tested, to derive the limit amounts. This approach helps in avoiding regrettable substitution with regard to the product aspect (o), for which the performance requirement is proposed. The potential trade-off with other product aspects should be flagged and further investigated, for example concerning the durability.

Regarding the technical / economic feasibility of substitution, both alternatives to PTFE explored in the current Case Study are already available on the market. More specifically, according to the stakeholder consultation done in the context of the PFAS restriction proposal, silicone-based and paraffin-based (i.e. hydrocarbon-based) alternatives for the hydrophobic treatment of textiles, i.e. a treatment rendering the textile water repellent, have also demonstrated their potential in all consumer apparel applications in recent years - with substitution from PFAS-based treatments to alternative treatments having started in 2008. No mandatory technical requirements for consumer apparel were identified. Also in this case, a deeper evaluation could be done to identify all the possible trade-off related to other technical performances of the material, for example in terms of breathability.

According to the positive outcome of the present Step, the assessment can proceed with the assessment of safety and sustainability aspects (Step 2).

Step 2_Assessment of alternatives (safety and sustainability)

According to the section C2 of the current method, the alternative(s) identified and screened in the previous Step need to be further evaluated for their safety and sustainability aspects. The SSbD framework is proposed as a possible reference to carry out this assessment.

With regard to the safety aspects, as a first step, the presence of the alternative substance in relevant regulatory lists has been checked, complementing the evaluation by scoring the hazard properties of the alternatives against the target substance. Based on the data and resources available, the risk profile of the alternative(s) could not be considered.

With regard to the sustainability aspects, the environmental footprint of the Base Case (that includes the target substance) has been compared with the two alternative Base Cases (that includes the CF and inventory flows of the tested alternatives).

Safety assessment

With specific regard to the hazard-based evaluation of the alternatives, the framework suggests that when the chemical under investigation is a component of a mixture (a chemical product), which is the case of the current analysis of alternatives, the available CLP classification of the main known components is considered and scored according to SSbD H criteria. Specifically, for the alternative products chosen in the present study, no public data concerning the full composition were available to complement the information gathered from the BREF. The same approach has been applied to flag the presence of the main known components in regulatory list (for example the REACH Candidate List, REACH restriction list), or under consideration for the inclusion in such lists.

With regard to the risk-based evaluation of the alternatives, in the context of the current Case Study the public data did not allow for an investigation; specifically, it was not possible to check the risk profile (including any exposure scenario from extended SDS) of the main components identified for each chemical alternative, to further qualify/quantify the safety aspect related to the life stages.

Silicone-based

According to the BREF, Silicone-based products are generally supplied as aqueous emulsions consisting of polysiloxane-active substances (dimethylpolysiloxane and modified derivatives), emulsifiers, hydrotropic agents (glycols) and water. Various types of silicone polymers based on PDMS have been shown to contain residual levels of cyclic volatile methyl siloxanes due to residues from manufacturing processes, e.g. octamethylcyclotetrasiloxane (D4) and decamethylcyclopentasiloxane (D5).

The **Table 57** below reports the information available for the known components of the silicone-based alternative, including the CLP classification, the presence in regulatory lists and the comparison with SSbD Step 1 criteria.

Table 57. Information available for CLP classification of silicone-based product components.

Alternative recipes	Substances (CAS)	CLP classification and H score	Presence in regulatory lists
Silicone-based	**Dimethylpolysiloxane (CAS: 107-51-7)** as main components (alternative 1)	Self-classification: Flam. Liq.,3 (H226) H3 criterium	Under evaluation as SVHC (vPvB) Under evaluation as PBT Potential red flag
	octamethylcyclotetrasiloxane (D4, CAS 556-67-2), decamethylcyclopentasiloxane (D5, CAS 541-02-6), dodecamethylcyclohexasiloxane (D6, CAS: 540-97-6) as possible impurities	D4: harmonized classification: Aq. Chr. 1/ Repr. 2 (H410/H361f) D5: self classification- Not classified D6: self classification- Not classified	Entry 70 Annex XVII REACH Candidate List as SVHC (vPvB) Proposed for inclusion in Annex I of POP Regulation Red flag

Source: JRC's own elaboration.

Wax-based

Wax emulsions are complex colloidal systems where wax particles are stabilized in water with the help of surfactants. According to BREF, wax-based formulations consist of emulsion ca. 25 % of a paraffin and 5 – 10 % of zirconium-, aluminium-based salts. The remaining share is assumed being water.

The **Table 58** below reports the information available for the known components of the wax-based alternative, including the CLP classification, the presence in regulatory lists and the comparison with SSbD Step 1 criteria.

Table 58. Information available for CLP classification of wax-based product components.

Alternative recipes	Substances (CAS)	CLP classification	Presence in regulatory lists
Wax-based	**Paraffin wax (CAS: 8002-74-2)** main component (alternative 2)	Self classification: Not classified	none
aluminium-based salts	Aluminium sulfate (CAS: 7784-24-9) auxiliary	Self classification: Eye Dam. 1 (H318)	none

Source: JRC's own elaboration.

Evaluation of safety aspects

As explained in the previous paragraph, the data available only allowed for an evaluation and a comparison based on the hazard classification and presence in regulatory lists of the main, known component of the alternative mixture. According to this approach, the paraffin wax (wax-based alternative) showed a better performance comparing the dimethylpolysiloxane (silicone-based alternative), since the first is not classified or self-classified under CLP while the second has Flam. Liq.,3 (H226) CLP classification and does meet the H3 criterion of SSbD. In addition, the scrutiny of dimethylpolysiloxane as a possible PBT and the potential inclusion in the Candidate List as SVHC as vPvB represents a possible alert for regrettable substitution. According to the information available, D4, D5, D6 impurities, which are SVHC substances and are restricted under REACH Annex XVII, might also be present in the silicone-based alternative. For these reasons, the hazardous profile silicone-based alternative can be considered less favourable than the wax-based.

Following the same approach, the hazard properties of the alternatives are also qualitatively compared with the ones of the target substance.

The **Table 59** below reports the information for the PTFE, including the CLP classification, the presence in regulatory lists and the comparison with SSbD Step 1 criteria.

Table 59. Information available for CLP classification of PTFE-based product.

Target	Substances (CAS)	CLP classification and H score	Presence in regulatory lists
PTFE	9002-84-0 main component	Self-classification: Not classified	REACH Restriction proposal on PFAS (ECHA) Potential red flag
PFOA	335-67-1 (as possible impurities)	Harmonized classification: Acute Tox. 4 (swallowed)/ Eye Dam. 1/ Acute Tox 4 (inhalation)/ Carc. 2/ Lact./ STOT RE 1 (liver)/ Repr. 1B (H302/H318/ H332/H351/H362/H372/H360D)	Candidate List as SVHC, POP Annex I Red flag

Source: JRC's own elaboration.

Overall, as shown in **Table 60**, according to the analysis, the wax-based alternative shows the best safety performance with regard to the hazard profile, with a lower possibility of being in the future targeted addressed by regulatory actions (thus, with higher chances of avoiding regrettable substitution). A more complete evaluation would be possible by enlarging the quality and representativeness of data (for example analysing more product formulations and considering the concentration) and including risk-based considerations.

The **Table 60** below includes a summary of the hazard profile, including regulatory actions, of the target substance and the identified alternatives.

Table 60. Comparison of target substance and alternatives (main components).

Target - PTFE-based	Alt. 1 - Silicone-Based	Alt. 2 - Wax-based
The main component (PTFE) results proposed for a REACH restriction and has no CLP classification Possible presence of impurities in the formulation (PFOA) that are identified as POP	The main component results under evaluation as PBT and as SVHC (Dimethylpolysiloxane) and a CLP classification of H226 and an H score of yellow Possible presence of impurities in the formulation (D4, D5, D6) that are in REACH restriction and in CL, while proposed for inclusion in Annex I of POP Regulation	The main component (Paraffin wax) has no CLP classification Presence of auxiliary (aluminium-based salts) with CLP classification as H318
Potential red flag due to REACH restriction proposal	Potential red flag due to regulatory scrutiny	The main component is neither listed in regulatory list nor under scrutiny/proposed for inclusion

Source: JRC's own elaboration.

Sustainability assessment

According to the method proposed in section C2, following the indications of the PEF methods, the single score resulting from the LCA of the BC (PTFE) should be calculated and compared with the single score obtained from the alternative scenario (Silicone-based and Wax-based), considering all the life stages.

The **Table 61** below shows the Results of LCA analysis over the entire life stages of the product expressed as single score for the target substance and the alternatives.

Table 61. Results of LCA analysis over the entire life stages of the product expressed as single score for the target substance and the alternatives. In the context of a full PEF study, also uncertainty[475] and sentisitivity[476] analyses are suggested to be performed.

Impact categories	Unit	PTFE	Silicone-based	Wax-based
Total	Pt	1.12E-02	1.10E-01 Score: 0 (no improvement)	1.09E-02 Score: 1 (0- 5% improvement)
Acidification	Pt	1.22E-03	1.23E-03	1.21E-03
Climate change	Pt	1.91E-03	1.72E-03	1.68E-03
Ecotoxicity, freshwater	Pt	1.81E-03	8.01E-03	1.97E-03
Particulate matter	Pt	1.36E-03	1.36E-03	1.35E-03
Eutrophication, marine	Pt	8.51E-04	8.53E-04	8.51E-04
Eutrophication, freshwater	Pt	2.04E-04	2.04E-04	2.03E-04
Eutrophication, terrestrial	Pt	8.81E-04	8.83E-04	8.80E-04
Human toxicity, cancer	Pt	1.27E-04	1.18E-04	1.17E-04

475 Uncertainty analysis – procedure for assessing uncertainty in the results of a PEF study due to data variability and choice-related uncertainty.

476 Sensitivity analysis – systematic procedures for estimating the effects of the choices made regarding methods and data on the results of a PEF study.

Impact categories	Unit	PTFE	Silicone-based	Wax-based
Human toxicity, non-cancer	Pt	1.39E-04	9.30E-02	2.47E-04
Ionising radiation	Pt	2.39E-05	2.45E-05	2.37E-05
Land use	Pt	4.59E-04	4.60E-04	4.59E-04
Ozone depletion	Pt	2.46E-04	6.63E-07	3.12E-07
Photochemical ozone formation	Pt	1.44E-04	1.46E-04	1.42E-04
Resource use, fossils	Pt	6.16E-04	6.41E-04	6.10E-04
Resource use, minerals and metals	Pt	1.61E-04	1.48E-04	1.45E-04
Water use	Pt	1.01E-03	1.01E-03	1.00E-03

Source: JRC's own elaboration.

Evaluation of sustainability aspects

According to the results, the wax-based alternative (1.09E-02 Pt) shows the lower total score, followed by the PTFE (1.12E-02 Pt), while the Silicone-based alternative shows the higher environmental impact (1.10E-01 Pt). Comparing the wax-based alternative with the target substance, the wax-based alternative shows an improvement in all the impact categories with the only exemption of Ecotoxicity freshwater and Human toxicity, non cancer. Instead, comparing the wax-based alternative with the silicone-based alternative, the wax-based alternative shows an improvement for all the impact categories.

It should be noted that, while the CF was available for the identified components of the two alternatives, the CF related to the PTFE was not available. This limitation reflects in the robustness of the comparison between the target substance and the alternative, since the impact due to the emissions of PTFE cannot be accounted, while it is considered for the alternatives.

With regard to the sustainability profile of the alternatives, the wax-based alternative shows a better performance as single score, comparing to the Silicon-based alternative and also comparing to the target substance (PTFE).

Output of safe and sustainability assessment

According to the results of this preliminary safety (limited to the hazard profile) and sustainability assessment, only the wax-based alternative showed an improvement in both the safety and sustainability aspects comparing with the target substance, while the silicone-based does not improve neither the safety, nor the sustainability aspect.

Step 3_Potential trade-offs

Despite both the alternatives evaluated are already available on the market and the substitution seems feasible from an economic point of view, only the wax-based alternative is suggested to be selected for the final evaluation of the trade-off between the different aspects considered in the assessment.

According to the literature reviewed (BREF textile, 2023; REACH Annex XV of PFAS proposal, 2023; Forsman et al., 2020[477]), for the wax-based alternative potential trade-off in terms of technical performance seems possible and would deserve a further investigation, for example concerning the

477 Nina Forsmana, Leena-Sisko Johanssona, Hanna Koivulab, Matilda Tuurec, Pirjo Kääriäinenc, Monika Österberga. Open coating with natural wax particles enables scalable, non-toxic hydrophobation of cellulose-based textiles. Carbohydrate Polymers 227 (2020). Available at: https://doi.org/10.1016/j.carbpol.2019.115363.

hydrophobicity and the breathability of the materials and consequently the comfort. Potential trade-off among the product aspects should also be further investigated. For example, it was noted that the fluorine-free water-repellent are less stable (temperature, sun light), so other storage conditions might be necessary.

Overall, the results of the current assessment are reported below:

- Chemical alternatives to PTFE used as finishing agent for water-repellence exist on the market; it should be also noted that functional alternatives exist, for example alternative technologies relying on spinning and weaving of the textile have also been identified as a chemical-free option for providing water repellence. Such techniques are based on control of the surface roughness and weaving density. This technology has not been properly assessed in the current case study, so it is not possible to conclude on their safety and sustainability performance as well on the possible trade-off with the other aspects considered in the evaluation of the alternatives;
- Among the two chemical alternatives identified, the wax-based alternative shows a better performance in terms of safety and sustainability aspects compared with the silicone-based and also comparing the target substance;
- For wax-based alternative, trade-offs seems possible with specific regard to technical performance and with regard to other product aspects.

Overall, the results from the current case study show that chemical alternatives used as water-repellent agent as substitute of PTFE already exist in the market; for the wax-based alternative, the risk of regrettable substitution seems negligible. The **Table 62** below, summarises the output of the analysis of alternatives.

Table 62. Results of the analysis of alternatives.

Target substance	Functional requirements	Alternative(s) identified	Type of evaluation	Technical and economic feasibility	Safety and Sustainability aspects	Acceptable trade-off
PTFE	water resistance	**Silicone-based**	Qualitative/ quantitative Uncertainty; high	Feasible, alternatives already on the market. Possible trade-off for technical performance and with other product aspects	Worst performance than Wax-based and PTFE	Considered as possible regrettable substitution
PTFE	water resistance	**Wax-based**	Qualitative/quantitative Uncertainty; high	Feasible, alternatives already on the market. Possible trade-off for technical performance and with other product aspects	Better performance than Silicone-based and PTFE	Considered as possible suitable alternative

Source: JRC's own elaboration.

As mentioned throughout the whole section, more data would be needed to determine the representativeness of the evaluation, to further explore the acceptability of the trade-off and, overall, to reduce the uncertainty of the assessment. Indeed, as indicated at the beginning of the current case study, the main objective pursued is to test and illustrate the working of the methodology. It should be then remarked here that the results from all the steps of the current evaluation of the alternative are subject to a high degree of uncertainty, mainly due to the limited availability of data (only from public sources) and limited knowledge of the value chain.

This uncertainty affecting the results derives from:

— Step 1, concerning the availability of alternatives on the market that offer the same technical performance, where there could be more alternatives available, including functional alternatives, comparing the two chemical alternatives selected for the investigation;

— Step 2, concerning the safety and sustainability profiles of the chemical alternatives, where the safety aspect was only qualitatively evaluated from the hazard perspective, focusing only on the main known components of the chemical alternative, without a risk-based evaluation; with regard to the sustainability aspect, no margin of error was considered in the LCA modelling;

— Step 3, concerning the evaluation of possible trade-offs (between all the aspects considered in the assessment and also with other product aspects that are addressed by ESPR), while the technical and economic criteria to assess such trade-offs from a value-chain perspective, were not available.

The **Box 11** in next page, provides an overview of the lesson learnt from testing of C2.

Box 11. Comments and lessons learnt from testing of Section C2: Proposed approach for the evaluation of alternatives (preventing regrettable substitution).

The proposed methodology supports the systematic identification and evaluation of the alternatives available on the market, in case a substance is proposed for performance requirement (target substance), in order to avoid a regrettable substitution. Following a tiered approach, the methodology guides in the evaluation of different aspects, starting from the technical economic feasibility of substitution as a first screening step and proceeding, in case suitable alternatives are available, with the evaluation of safety and sustainability aspects and finally summarizing the results in order to consider the potential trade-off related to the substitution.

With regard to the evaluation of safety and sustainability aspects of the alternative, the SSbD framework can represent a useful support, especially regarding an envisaged chemical substitution, but the reader should also be aware that at the time of the current case study, the SSbD framework is still in the operationalization phase and will be subject to revision.

Overall, the involvement of stakeholders is considered pivotal to increase the quality and the representatively of the data and consequently of the evaluation, reducing the uncertainty of the conclusions (for example, due to the lack of criteria to accept or refuse a trade-off). In the context of the current Case Study, only a limited desktop investigation was possible, entirely relying on publicly available data, so that only a semi/quantitative evaluation has been done. In addition, it should be remarked that while only chemical substitution was evaluated, it is highly recommended to focus also efforts on potential functional substitution options.

Although the uncertainty associated to the evaluation is substantial, the application of the methodology is nonetheless considered solid enough to flag possible regrettable substitution and to inform the Preparatory Study regarding the proposal of performance requirements.

6.4 Inventory of substances identified under the worst-case scenario for each function from BREF for textiles and complementary sources

Table 63. List of alternative substances identified in the inventory for each function.

Steps in Raw material acquisition and pre-processing and Manufacturing stages	Materials	Function	Substances	CAS number	Reason as the most hazardous and source
Agricultural phase	cotton, wool, cashmere	Pesticide	Diazinon (wool, cashmere)	333-41-5	Organohalogens, organophosphorus compounds and biocides are among the polluting substances listed for emission control in the IED. Worldwide, the most common ectoparasiticides used for treating sheep are diazinon (OP), propetamphos (OP), cypermethrin (SP) and cyromazine (fly-specific IGR) (BREF)
			Cypermethrin (wool, cashmere, cotton)	52315-07-8	see above
			Cyromazine (wool, cashmere)	66215-27-8	see above
			Propetamphos (wool, cashmere)	31218-83-4	see above
			Chlorpyrifos (cotton)	2921-88-2	Possible pesticides (residues) detected in the cotton products include chlorpyrifos, malathion, profenofos and cypermethrin (BREF)
			Profenofos (cotton)	41198-08-7	see above
			Malathion (cotton)	121-75-5	see above
Fibre production[478]	viscose	Solvent	Carbon disulphide	75-15-0	n/a
		Acid agent	Zinc sulphate	7733-02-0	n/a
		solvent	Sodium hydroxide	1310-73-2	n/a
		solvent	Sulphuric acid	7664-93-9	n/a
		delustering agent	Titanium dioxide	13463-67-7	Suspected to be carcinogenic and present in the market in the nanomaterial form (REACH Registration data)[479]
Spinning of fibres	cotton, wool, cashmere, viscose	Lubricant	White mineral oil	8042-47-5	- Disadvantages of high add-on, low temperature stability (they smoke during high-temperature treatments), poor biodegradability, presence of

[478] Note: the BREF for textiles does not cover the production of man-made fibres. These are addressed in the BREF on polymers. In the Case Study, as an example, the substances used in the manufacturing of viscose fibres are considered based on data from BREF on polymers.

[479] https://www.echa.europa.eu/substance-information/-/substanceinfo/100.033.327.

Steps in Raw material acquisition and pre-processing and Manufacturing stages	Materials	Function	Substances	CAS number	Reason as the most hazardous and source
					polyaromatic hydrocarbons and generation of difficult-to-sediment sludge in biological wastewater treatment plants (BREF) - The use of mineral oils is declining. Because of their low cost, however, they are still widely used in applications where cheap products are needed (mainly as coning oils and, to a lesser extent nowadays, as wool processing auxiliaries). (BREF)
			Silicones (e.g. copolymers of silicone-like polydimethylsiloxane (PDMS) with glycols)	9006-65-9	non-biodegradable and difficult to remove without scouring assistants (BREF)
		Surfactant (as emulsifier)	NPEOs (non ionic)	9016-45-9	Toxic to aquatic life (BREF)
			Ethylene oxide (non ionic)	75-21-8	Hard to biodegrade (BREF)
			Propylene oxide (non ionic)	75-56-9	See above
			Fatty amine ethoxylates (non ionic) (no example chemicals in BREF): Tallow amine ethoxylate Coco amine ethoxylate Stearyl amine ethoxylate Oleyl amine ethoxylate Lauryl amine ethoxylate	61791-26-2 61791-14-8 26635-93-8 26635-94-9 31017-83-1	See above
			Lignin sulphonates (anionic) (no example chemicals in the BREF) e.g lignosulfonic acid, sodium salt	8061-51-6	Hard to biodegrade (BREF) (no example chemicals)
			Condensation products of naphthalene sulphonic acid with formaldehyde (anionic) e.g. Naphthalene Sulfonic Acid-Formaldehyde Condensate, Sodium Salt	*Not clearly identified* 9084-06-4 or alternative 1: 85586-40-9 or alternative 2: 85536-87-4	Hard to biodegrade (BREF)
			Quaternary ammonium compounds (cationic) e.g. distearyl dimethyl ammonium chloride	107-64-2	highest toxicity of all classes of surfactants, but <u>very rarely applied</u> (BREF)

Steps in Raw material acquisition and pre-processing and Manufacturing stages	Materials	Function	Substances	CAS number	Reason as the most hazardous and source
			Amine oxide (amphoteric)	*Not clearly identified* 2605-79-0 or alternative 1: 3332-27-2 or alternative 2: 1643-20-5 or alternative2: 2605-78-9	Amphoteric surfactants are expensive and are not widely used in the textile industry (BREF)
		Biocide	Formaldehyde-containing compounds (e.g. Formaldehyde)	50-00-0	Concerning wet scrubbing, most compounds dissolved in the scrubbing liquor can be decomposed biologically. However, substances may be introduced into the wastewater that have toxic potential for bacteria (e.g. from biocide finishing), such as formaldehyde, triclosan, isothiazolinone or mercaptobenzimidazole (BREF)
			Heterocyclic compounds (imidazol and isothiazolinone derivatives) Isothiazolinone	2682-20-4	see above
			Heterocyclic compounds (imidazol and isothiazolinone derivatives) Imidazole	288-32-4	see above
Scouring	cotton, wool, cashmere, viscose	Surfactant	see surfactant (as emulsifier) above		
Spinning in yarn	all	see spinning in fibres above			
Knitting (fabric production)	all	Lubricant	see lubricant above		
Washing (pre-treatment)	all	Surfactant	see surfactant (as emulsifier) above		
		Complexing agent	Ethylenediaminetetraacetic acid (EDTA) (polycarboxylic acids)	60-00-4	poor bio-eliminability, which may pass undegraded through the wastewater treatment systems. Their ability to form very stable complexes with metal makes the problem even more serious because they can mobilise heavy metals present in the effluent and release them in the receiving water (BREF, Table 4.18, N-content (eutrophication potential))
			Diethylenetriaminepentaacetic acid (DTPA) (polycarboxylic acids)	67-43-6	
			Tripolyphosphate (polyphosphates)	7758-29-4	BREF Table 4.18, P-content (eutrophication potential)

Steps in Raw material acquisition and pre-processing and Manufacturing stages	Materials	Function	Substances	CAS number	Reason as the most hazardous and source
			Diethylenetriaminepenta(methylenephosphonic acid) (DTPMP) (phosphonates)	15827-60-8	BREF Table 4.18, P-content (eutrophication potential) and no biodegradability
			Ethylenediaminetetra(methylenephosphonic acid) (EDTMP) (phosphonates)	1429-50-1	BREF Table 4.18, P-content (eutrophication potential) and no biodegradability
Bleaching	cotton, wool and cashmere	Bleaching agent	Sodium hypochlorite (cotton)	7681-52-9	AOX emissions (e.g. trichloromethane, carcinogenic) and other substances (dioxins in sludge, chlorine in air) (BREF)
			Hydrogen peroxide (cotton, wool and cashmere)	7722-84-1	- It requires the use of stabilisers (e.g. EDTA) that give rise to environmental problems. (BREF) - Because the bleaching agent of peroxide is anionic in nature (hydrophilic behaviour), it is not possible with this bleaching method to selectively destroy the coloured hydrophobic material present on natural fibres without attacking the polymer itself (BREF)
		Sequestering/stabilizer	see complexing agent above		
		Reductive	sodium dithionite	7775-14-6	sodium dithionite, the product is corrosive, irritant, flammable and has an unpleasant odour (BREF)
		Alkaline	Sodium hydroxide	1310-73-2	n/a
			sodium carbonate	497-19-8	n/a
		Surfactant	see surfactant above		
Direct dyeing[480]	cotton, viscose	Dye	Direct Black 38 (benzidine-based azo dye)	1937-37-7	Restricted, found in ECHA report (ECHA, 2009)[481] and listed in AFIRM Restricted Substance List (RSL)[482]
			Direct Orange 62 (benzidine-based azo dye)	12222-38-7	Direct Orange 62 has been classified as toxic by ETAD (BREF)
			Direct Blue 6 (benzidine-based azo dye)	2602-46-2	listed in AFIRM Restricted Substance List (RSL)

480 Note: general recipe for direct dyeing from BREF. The recipe reported in the BREF does not specify the amounts, so for these functions information provided by a textiles retailer are used.

481 ECHA, ANNEX XVII TO REACH, Entry 43 Azocolourants and Azodyes, https://echa.europa.eu/documents/10162/bd51087b-9917-b018-69ac-d7594315e2a9.

482 AFIRM Group, Restricted Substances List, https://afirm-group.com/afirm-rsl/.

Steps in Raw material acquisition and pre-processing and Manufacturing stages	Materials	Function	Substances	CAS number	Reason as the most hazardous and source
			Direct Red 28 (benzidine-based azo dye)	573-58-0	see above
			Direct Brown 95 (benzidine-based azo dye)	16071-86-6	see above
		Salt	Sodium chloride	7647-14-5	n/a
			sodium sulphate	7757-82-6	n/a
		Fixers (after treatment agent)	Formaldehyde condensation products with amines	94645-56-4	Environmental concerns arise when after-treating with formaldehyde condensation products or metal salts. The method using fixative cationic agents is, therefore, the most frequently applied. However, quaternary ammonium compounds are often non-biodegradable, toxic to fish and contain nitrogen. (BREF)
			quaternary ammonium compounds (cationic) e.g. distearyl dimethyl ammonium chloride	107-64-2	see above
		Wetting and dispersing i.e. surfactants	see surfactants above		
		Levelling agents	Polyvinylpyrrolidone	9003-39-8	BREF Table 2.20: Substances of environmental interest in the dyeing auxiliaries
		Alkaline	see alkaline above		
Disperse dyeing[483]	PES, r-PET, acrylic	Dye	Disperse Blue 35 (anthraquinone-based dye)	12222-75-2	Found in test report RI.SE, 2019[484] and listed in AFIRM Restricted Substance List (RSL)[485]
			Disperse Orange 37/76/59 (azo dye)	12223-33-5; 13301-61-6; 51811-42-8	see above
			Disperse Red 1 (azo dye)	2872-52-8	see above

483 Note: recipe based on Table 4.81: Recipe with alkali-clearable dyes and recipe with standard dyes for PES-CO blends). Added "carrier" for disperse dyes.

484 Research Institute of Sweden (RI.SE), REPORT Results of analyses for Classification and risk assessment of textiles for material recycling – Funded by Vinnova 2017- 2019, https://www.ri.se/sites/default/files/2020-11/Classification%20and%20risk%20assessment_analytical%20results.pdf.

485 AFIRM Group, Restricted Substances List, https://afirm-group.com/afirm-rsl/.

Steps in Raw material acquisition and pre-processing and Manufacturing stages	Materials	Function	Substances	CAS number	Reason as the most hazardous and source
			Disperse Yellow 39 (methine dye)	12236-29-2	see above
			Disperse Yellow 49 (methine dye)	54824-37-2; 6858-49-7	Found in test report Danish EPA[486] and listed in AFIRM Restricted Substance List (RSL)
			Disperse Blue 124 (monoazo compound)	61951-51-7	see above
		Carrier	1,2,4, trichlorobenzene (halogenated benzenes)	120-82-1	Toxic to humans, aquatic organisms and sewage sludge. (BREF) Listed in AFIRM RSL
			beta-methylnaphthalene (aromatic hydrocarbons)	91-57-6	Toxic to humans, aquatic organisms and sewage sludge. (BREF)
			O-phenylphenol (phenols)	90-43-7	see above
			Benzyl benzoate (carboxylic acid and their esters)	120-51-4	see above
		Salt	see salt above		
		pH adjuster	Acetic acid	64-19-7	higher specific COD (1 067 mg O2/g) compared to formic acid (COD= 235 mg O2/g) (BREF)
		Dispersing agent	Condensation products of naphthalene sulphonic acid with formaldehyde e.g. Naphthalene Sulfonic Acid-Formaldehyde Condensate, Sodium Salt	*Not clearly identified* 9084-06-4 or alternative 1: 85586-40-9 or alternative 2: 85536-87-4	- Hard to biodegrade (BREF) - soluble in water and poorly eliminable in common wastewater systems. (BREF)
			see surfactants (non ionic and anionic) above		
			Lignin sulphonates e.g lignosulfonic acid, sodium salt	8061-51-6	- Hard to biodegrade (BREF) (only type of lignosulphonic) - soluble in water and poorly eliminable in common wastewater systems. (BREF)
		Levelling agent	see fatty amine ethoxylated above		

486 The Danish Environmental Protection Agency, Survey of Selected Allergenic, Disperse Dyes in Clothes, 2014, https://www2.mst.dk/Udgiv/publications/2014/04/978-87-93178-43-4.pdf.

Steps in Raw material acquisition and pre-processing and Manufacturing stages	Materials	Function	Substances	CAS number	Reason as the most hazardous and source
			Benzylbenzoate	120-51-4	BREF Table 4.65: Aquatic toxicity (algae) of raw materials used for the formulation of levelling agents for PES dyeing
			Butylbenzoate	136-60-7	see above
		Detergent	see surfactants (non ionic and anionic) above		
		Equalisation agent	*(not defined in BREF)*		
Reactive dyeing[487]	wool, cashmere, nylon 6.6	Dye	Reactive Blue 72 (phthalocyanine dye)	61968-93-2	BREF Table 8.19: Overview of the ecological properties of reactive dyes (low fixation rate and low bioeliminability) heavy metals can be present both as impurities from the production process (limits have been set by ETAD) and as an integral part of the chromophore especially in phthalocyanine dyes, which are widely used especially for blue and turquoise shades
			Reactive Black 5 (azo dye belonging to vinyl sulphone type)	17095-24-8	Not specific for this substance (it is one of the most important reactive dyestuffs in terms of volumes consumed) (BREF) BREF Table 8.19: Overview of the ecological properties of reactive dyes (low fixation rate and low bioeliminability)
		Salt	see salt above		
		pH adjuster	see pH adjuster above		
		Levelling agent	see fatty amine ethoxylated above		
		Washing agent (after treatment)	Ammonia	7664-41-7	n/a
Finishing (easy care/cross linking/no crease)	cotton, viscose	Easy care/cross linking agents	Hydroxymethyl urea (formaldehyde-rich)	1000-82-4	The emissions of formaldehyde, methanol and other volatile organic substances in the exhaust air (from curing and drying operations) and in the workplace (especially with melamine resins) represent the main environmental issue in the application of these agents (BREF)

487 Note: based on recipe in Table 2.10: Summary of the most common dyes and dyeing techniques for wool fibres. Added "salt" from Table 2.19: Amount of salt employed in cotton batch dyeing processes with reactive and direct dyes.

Steps in Raw material acquisition and pre-processing and Manufacturing stages	Materials	Function	Substances	CAS number	Reason as the most hazardous and source
			hydroxymethyl melamine (formaldehyde-rich)	*not found*	see above
			bis(methoxymethyl) melamine (formaldehyde-rich)	*not found;* - possible alternative 1: 3089-11-0 (hexa(methoxymethyl) melamine) - possible alternative 2: 68002-20-0 (methylated melamine-formaldehyde resin, 1,3,5-Triazine-2,4,6-triamine, polymer with formaldehyde, methylated)	see above
		Catalyst	Ammonium sulphate	7783-20-2	Ammonium salts (e.g. chloride, sulphate and nitrate) commonly used in the past, particularly with cross-linkers based on urea and formaldehyde or melamine, are in decline today, following the corresponding decline in importance of these cross-linking agents. (BREF)
			Ammonium nitrate	6484-52-2	see above
			Ammonium chloride	12125-02-9	see above
		Softners	[dispersion of] polysiloxanes (e.g. dimethyl polysiloxanes? mentioned for other functions in BREF)	161755-53-9; 9006-65-9 (dimethyl polysiloxanes)	These substances are responsible for emissions of VOCs in the exhaust air from curing and drying operations. The poor biodegradability of the above-mentioned polymer dispersions has also to be taken into account when considering water pollution (BREF)
			[dispersion of] polyethylene waxes (partially oxidised polyethylenes)	68441-17-8	see above

Steps in Raw material acquisition and pre-processing and Manufacturing stages	Materials	Function	Substances	CAS number	Reason as the most hazardous and source
			[dispersion of] polyacrylates (e.g. as in Polymer dispersions (aqueous formulations, 50% water) for Coating (BREF page 869): - poly(meth)acrylate (butyl, ethyl, methyl etc.); - polyacrylic acid; - polyacrylonitrile; - polyacryloamide)	9011-14-7 (Poly(methyl methacrylate)) 9003-63-8 (Poly(butyl methacrylate)) 9003-42-3 (Poly(ethyl methacrylate)) 9003-01-4 (polyacrylic acid) 9009-54-5 (polyurethane) 9003-05-8 (polyacryloamide)	see above
			[dispersion of] polyurethanes (e.g. as in Polymer dispersions (aqueous formulations, 50% water) for Coating (BREF page 869)	9009-54-5	see above
			dimethyldioctadecylammonium chloride (cationic softner - fatty acid condensation product)	107-64-2	see above
			spolyvinyl acetate (e.g. as in Polymer dispersions (aqueous formulations, 50% water) for Coating (BREF page 869)	9003-20-7	see above
Finishing (anti felt/anti shrink treatment-Hercosett process)[488]	wool, cashmere	Oxidant treatment	Sodium salt dichloroisocyanurate	2893-78-9	n/a but reported here since the amount in the recipe is explicitly mentioning this substance
			Sodium hypochlorite	7681-52-9	The oldest process is the one using sodium hypochlorite. However, since the development of active chlorine is difficult to control, wool fibre characteristics can be significantly changed, also giving irregular results.

488 Note: steps described in BREF for textiles. Quantitative data from Table 8.45: Standard recipe for the pretreatment for printing of wool with chlorine-containing substances.

Steps in Raw material acquisition and pre-processing and Manufacturing stages	Materials	Function	Substances	CAS number	Reason as the most hazardous and source
		neutralisation	Sodium carbonate (*not quantified in Table 8.45 BREF)*	497-19-8	n/a
		pH adjuster	see pH adjuster above		
		Anti-chlorine treatment	sodium bisulphite	7631-90-5	n/a
		Surfactant	see surfactant above		
		Resin/polymer	Polymer (PA) based resin with epichlorohydrin	*not found*	The formation of AOX is attributable not only to the oxidant, but also to the resin. In fact, the typical resin applied in the Hercosett process is a cationic polyamide whose manufacturing process involves the use of epichlorohydrin, which is another source of the chlorinated hydrocarbons in the effluent (BREF)
Finishing (water repellence and biocide)	all	Water-repellent	Polytetrafluoro ethylene (PTFE)	9002-84-0	It may contain PFOA impurities (Amec Foster Wheeler, 2020[489])
		Biocide	Benzothiazole derivative (assumed (benzothiazol-2-ylthio)methyl thiocyanate; TCMTB)	21564-17-0	n/a

Source: JRC's own elaboration based on and adapted from available sources.

Note: "n/a" means "not available" and indicates that no information about hazard or environmental-related issues are available for the specific substance.

[489] Amec Foster Wheeler Environment & Infrastructure GmbH (now part of Wood), The use of PFAS and fluorine-free alternatives in textiles, upholstry, carpets, leather and apparel, 2020, https://saicmknowledge.org/sites/default/files/resources/pfas_in_textiles_final_report_en.pdf.

Table 64. Suggested EF 3.1 datasets for the production of the substances and EF 3.1 characterization factors (CFs) corresponding to the CAS number, to be potentially considered for the life cycle inventory (LCI) for the environmental footprint.

Substances	CAS number	EF 3.1 suggested dataset	Name of the CF in EF 3.1
Diazinon (wool, cashmere)	333-41-5	Diazine-compound {GLO} | global average technology mix | production mix, at plant | 100% active substance | LCI result	Diazinon
Cypermethrin (wool, cashmere, cotton)	52315-07-8	Pyrethroid-compounds {GLO} | average technology mix | production mix at plant | 100% active substance | LCI result (proxy)	cypermethrin
Cyromazine (wool, cashmere)	66215-27-8	No EF dataset available	cyromazine
Propetamphos (wool, cashmere)	31218-83-4	Organophosphorus-compounds {GLO} | average technology mix | production mix at plant | 100% active substance | LCI result (proxy)	trans-isopropyl-3-[[(ethylamino)methoxyfosfinothioyl]oxy]crotonate
Chlorpyrifos (cotton)	2921-88-2	Organophosphorus-compounds {GLO} | average technology mix | production mix at plant | 100% active substance | LCI result (proxy)	Chlorpyrifos
Profenofos (cotton)	41198-08-7	Organophosphorus-compounds {GLO} | average technology mix | production mix at plant | 100% active substance | LCI result (proxy)	O-(4-bromo-2-chlorophenyl) O-ethyl S-propyl phosphorothioate
Malathion (cotton)	121-75-5	Organophosphorus-compounds {GLO} | average technology mix | production mix at plant | 100% active substance | LCI result (proxy)	malathion
Carbon disulphide	75-15-0	Modelled based on EcoInvent version 3.9.1	carbon disulphide
Zinc sulphate	7733-02-0	Zinc sulfate {GLO} | global average technology mix | production mix, at plant | 100% active substance | LCI result	zinc sulfate
Sodium hydroxide	1310-73-2	Sodium hydroxide production {EU+EFTA+UK} | technology mix | production mix, at plant | 100% active substance | LCI result	sodium hydroxide
Sulphuric acid	7664-93-9	Sulphuric acid production {EU+EFTA+UK} | technology mix | production mix, at plant | 100% active substance | LCI result	sulphuric acid
Titanium dioxide	13463-67-7	Titanium dioxide production {EU+EFTA+UK} | technology mix | production mix, at plant | 100% active substance | LCI result	titanium dioxide
White mineral oil	8042-47-5	Diesel mix at refinery {EU+EFTA+UK} | from crude oil | production mix, at refinery | 10 ppm sulphur, 7.23 wt.% bio components | LCI result (proxy)	white mineral oil
Silicones (e.g. copolymers of silicone like polydimethylsiloxane (PDMS) with glycols)	9006-65-9	Polysiloxane {GLO} | Technology mix | Production mix, at plant | LCI result (proxy) OR Antifoaming agent, silicone emulsion production {GLO} | technology mix | production mix, at plant | 100% active substance | LCI result (proxy) OR FROM EI: Polydimethylsiloxane {GLO}| polydimethylsiloxane production | Cut-off, U	n/a

Substances	CAS number	EF 3.1 suggested dataset	Name of the CF in EF 3.1
NPEOs (non ionic)	9016-45-9	Created starting from EcoInvent version 3.9.1 database	nonylphenol ethoxylated
Ethylene oxide (non ionic)	75-21-8	Non-ionic surfactant, ethyleneoxidederivate production {GLO} | technology mix | production mix, at plant | 100% active substance | LCI result	ethylene oxide
Propylene oxide (non ionic)	75-56-9	Propylene oxide production {GLO} | technology mix | production mix, at plant | 100% active substance | LCI result	propylene oxide
Fatty amine ethoxylates (non ionic) (no example chemicals in BREF): Tallow amine ethoxylate Coco amine ethoxylate Stearyl amine ethoxylate Oleyl amine ethoxylate Lauryl amine ethoxylate	61791-26-2 61791-14-8 26635-93-8 26635-94-9 31017-83-1	Modelled first the fatty amine production and then the fatty amine ethoxylated production	n/a
Lignin sulphonates (anionic) (no example chemicals in the BREF) e.g lignosulfonic acid, sodium salt	8061-51-6	The process can be modelled as a mixture of the following: Unbleached kraft pulp, hardwood {WORLD (WITHOUT EU+EFTA+UK, US AND CA)} | technology mix | production mix, at plant | dry mass 0.9, carbon content, non-fossil 0.494 | LCI result + Sodium sulphate production {EU+EFTA+UK} | technology mix | production mix, at plant | 100% active substance | LCI result + Formaldehyde production {EU+EFTA+UK} | technology mix | production mix, at plant | 100% active substance | LCI result	lignosulfonic acid, sodium salt
Condensation products of naphthalene sulphonic acid with formaldehyde (anionic) e.g. Naphthalene Sulfonic Acid-Formaldehyde Condensate, Sodium Salt	*Not clearly identified* 9084-06-4 or alternative 1: 85586-40-9 or alternative 2: 85536-87-4	The process can be modelled as a mixture of the following: Naphthalene sulfonic acid production {EU+EFTA+UK} | technology mix | production mix, at plant | 100% active substance | LCI result + Formaldehyde production {EU+EFTA+UK} | technology mix | production mix, at plant | 100% active substance | LCI result	* 5-(benzoylamino)-4-hydroxy-3-((1-sulpho-6-((2-(sulphooxy)ethyl)sulphonyl)-2-naphthyl)azo)naphthalene-2,7-disulphonic acid, sodium salt /n/n OR ** 7-acetamido-4-hydroxy-3-[[4-[[2-(sulphooxy)ethyl]sulphonyl]phenyl]azo]naphthalene-2-sulphonic acid, sodium salt
Quaternary ammonium compounds (cationic) e.g. distearyl dimethyl ammonium chloride	107-64-2	The process can be modelled as a mixture of the following: Calcium stearate production {GLO} | technology mix | production mix, at plant | 100% active substance | LCI result + Ammonia, as 100% NH3 production {EU+EFTA+UK} | technology mix | production mix, at plant | 100% active substance | LCI result + Dichloromethane production {EU+EFTA+UK} | technology mix | production mix, at plant | 100% active substance | LCI result +	dimethyldioctadecylammonium chloride

Substances	CAS number	EF 3.1 suggested dataset	Name of the CF in EF 3.1
		Sodium hydroxide production {EU+EFTA+UK} | technology mix | production mix, at plant | 100% active substance | LCI result	
Amine oxide (amphoteric)	*Not clearly identified* 2605-79-0 or 3332-27-2 or 1643-20-5 or 2605-78-9	Amine oxide production {EU+EFTA+UK} | technology mix | production mix, at plant | 100% active substance | LCI result	* decyl(dimethyl)amine oxide or ** dimethyl(tetradecyl)amine oxide or *** dodecyl(dimethyl)amine oxide or **** octyldimethylamine oxide
Formaldehyde-containing compounds (e.g. Formaldehyde)	50-00-0	Formaldehyde production {EU+EFTA+UK} | technology mix | production mix, at plant | 100% active substance | LCI result	formaldehyde
Heterocyclic compounds (imidazol and isothiazolinone derivatives) Isothiazolinone	2682-20-4	Benzisothiazolinone (1,2-benzisothiazolin-3-one) {GLO} | Technology mix | Production mix, at plant | LCI result (proxy)	1,2-benzisothiazol-3(2h)-one 1,1-dioxide 1,2-benzisothiazol-3(2h)-one 1,1-dioxide, calcium salt 1,2-benzisothiazolin-3-one 2-methyl-2H-isothiazol-3-one
Heterocyclic compounds (imidazol and isothiazolinone derivatives) Imidazole	288-32-4	Benzimidazole-compound production {GLO} | technology mix | production mix, at plant | 100% active substance | LCI result (proxy) OR Imidazole {RER}| imidazole production | Cut-off, U	imidazole
Ethylenediaminetetraacetic acid (EDTA) (polycarboxylic acids)	60-00-4	EDTA production {EU+EFTA+UK} | technology mix | production mix, at plant | 100% active substance | LCI result	EDTA
Diethylenetriaminepentaacetic acid (DTPA) (polycarboxylic acids)	67-43-6	Modelled from EcoInvent version 3.9.1	N-carboxymethyliminobis(ethylenenitrilo)tetra(acetic acid)
Tripolyphosphate (polyphosphates)	7758-29-4	Sodium tripolyphosphate production {EU+EFTA+UK} | technology mix | production mix, at plant | 100% active substance | LCI result	pentasodium triphosphate
Diethylenetriaminepenta(methylenephosphonic acid) (DTPMP) (phosphonates)	15827-60-8	No EF and no EcoInvent datasets available	[[(phosphonomethyl)imino]bis[ethane-2,1-diylnitrilobis(methylene)]]tetrakis phosphonic acid
Ethylenediaminetetra(methylenephosphonic acid) (EDTMP) (phosphonates)	1429-50-1	No EF and no EcoInvent datasets available	n/a
Sodium hypochlorite (cotton)	7681-52-9	Sodium hypochlorite production {EU+EFTA+UK} | technology mix | production mix, at plant | 100% active substance | LCI result	sodium hypochlorite

Substances	CAS number	EF 3.1 suggested dataset	Name of the CF in EF 3.1
Hydrogen peroxide (cotton, wool and cashmere)	7722-84-1	Hydrogen peroxide, 100% production {EU+EFTA+UK} | technology mix | production mix, at plant | 100% active substance | LCI result	hydrogen peroxide
sodium dithionite	7775-14-6	Sodium dithionite production {EU+EFTA+UK} | technology mix | production mix, at plant | 100% active substance | LCI result	disodium dithionite
Sodium hydroxide	1310-73-2	Sodium hydroxide production {EU+EFTA+UK} | technology mix | production mix, at plant | 100% active substance | LCI result	sodium hydroxide
sodium carbonate	497-19-8	Sodium bicarbonate production {EU+EFTA+UK} | technology mix | production mix, at plant | 100% active substance | LCI result	disodium carbonate
Direct Black 38 (benzidine-based azo dye)	1937-37-7	Modeled as Benzidine (based on EcoInvent version 3.9.1)	C.I. Direct Black 38
Direct Orange 62 (benzidine-based azo dye)	12222-38-7	Modeled as Benzidine (based on EcoInvent version 3.9.1)	n/a
Direct Blue 6 (benzidine-based azo dye)	2602-46-2	Modeled as Benzidine (based on EcoInvent version 3.9.1)	C.I. Direct Blue 6
Direct Red 28 (benzidine-based azo dye)	573-58-0	Modeled as Benzidine (based on EcoInvent version 3.9.1)	disodium 3,3'-[[1,1'-biphenyl]-4,4'-diylbis(azo)]bis(4-aminonaphthalene-1-sulphonate)
Direct Brown 95 (benzidine-based azo dye)	16071-86-6	Modeled as Benzidine (based on EcoInvent version 3.9.1)	disodium [5-[[4'-[[2,6-dihydroxy-3-[(2-hydroxy-5-sulphophenyl)azo]phenyl]azo][1,1'-biphenyl]-4-yl]azo]salicylato(4-)]cuprate(2-)
Sodium chloride	7647-14-5	Sodium chloride powder production {EU+EFTA+UK} | technology mix | production mix, at plant | 100% active substance | LCI result	sodium chloride
sodium sulphate	7757-82-6	Sodium sulphate production {EU+EFTA+UK} | technology mix | production mix, at plant | 100% active substance | LCI result	disodium sulfate
Formaldehyde condensation products with amines	94645-56-4	Melamine formaldehyde resin production {EU+EFTA+UK} | technology mix | production mix, at plant | 100% active substance | LCI result	n/a
quaternary ammonium compounds (cationic) e.g. distearyl dimethyl ammonium chloride	107-64-2	This process can be modelled as a mixture of the following: Calcium stearate production {GLO} | technology mix | production mix, at plant | 100% active substance | LCI result + Ammonia, as 100% NH3 production {EU+EFTA+UK} | technology mix | production mix, at plant | 100% active substance | LCI result + Dichloromethane production {EU+EFTA+UK} | technology mix | production mix, at plant | 100% active substance | LCI result +	dimethyldioctadecylammonium chloride

Substances	CAS number	EF 3.1 suggested dataset	Name of the CF in EF 3.1
		Sodium hydroxide production {EU+EFTA+UK} | technology mix | production mix, at plant | 100% active substance | LCI result	
Polyvinylpyrrolidone	9003-39-8	Modelled Vinylpyrrolidone production	n/a
Disperse Blue 35 (anthraquinone-based dye)	12222-75-2	Modelled Anthraquinone production	n/a
Disperse Orange 37/76/59 (azo dye)	12223-33-5; 13301-61-6; 51811-42-8	Aniline production {EU+EFTA+UK} | technology mix | production mix, at plant | 100% active substance | LCI result (proxy)	n/a
Disperse Red 1 (azo dye)	2872-52-8	Aniline production {EU+EFTA+UK} | technology mix | production mix, at plant | 100% active substance | LCI result (proxy)	n/a
Disperse Yellow 39 (methine dye)	12236-29-2	no EF dataset and no EcoInvent dataset available	n/a
Disperse Yellow 49 (methine dye)	54824-37-2; 6858-49-7	no EF dataset and no EcoInvent dataset available	n/a
Disperse Blue 124 (monoazo compound)	61951-51-7	Aniline production {EU+EFTA+UK} | technology mix | production mix, at plant | 100% active substance | LCI result (proxy)	n/a
1,2,4, trichlorobenzene (halogenated benzenes)	120-82-1	Trichloroethylene production {EU+EFTA+UK} | technology mix | production mix, at plant | 100% active substance | LCI result	1,2,4-trichlorobenzene
beta-methylnaphthalene (aromatic hydrocarbons)	91-57-6	1,4-dimethylnaphthalene {GLO} | production mix, at plant | per kg active ingredient | LCI result	2-methylnaphthalene
O-phenylphenol (phenols)	90-43-7	Phenol production {EU+EFTA+UK} | technology mix | production mix, at plant | 100% active substance | LCI result (proxy)	o-phenylphenol
Benzyl benzoate (carboxylic acid and their esters)	120-51-4	This process can be modelled as a mixture of the following: Benzyl alcohol production {EU+EFTA+UK} | technology mix | production mix, at plant | 100% active substance | LCI result + Benzoic acid production {GLO} | technology mix | production mix, at plant | 100% active substance | LCI result	benzyl benzoate
Acetic acid	64-19-7	Acetic acid production {EU+EFTA+UK} | technology mix | production mix, at plant | 100% active substance | LCI result	acetic acid
Condensation products of naphthalene sulphonic acid with formaldehyde e.g. Naphthalene Sulfonic Acid-Formaldehyde Condensate, Sodium Salt	*Not clearly identified* 9084-06-4 or alternative 1 85586-40-9 or alternative 2 85536-87-4	This process can be modelled as a mixture of the following: Naphthalene sulfonic acid production {EU+EFTA+UK} | technology mix | production mix, at plant | 100% active substance | LCI result + Formaldehyde production {EU+EFTA+UK} | technology mix | production mix, at plant | 100% active substance | LCI result	alternative 1: 5-(benzoylamino)-4-hydroxy-3-((1-sulpho-6-((2-(sulphooxy)ethyl)sulphonyl)-2-naphthyl)azo)naphthalene-2,7-disulphonic acid, sodium salt /n/n alternative 2: 7-acetamido-4-hydroxy-3-[[4-[[2-(sulphooxy)ethyl]sulphonyl]phenyl

Substances	CAS number	EF 3.1 suggested dataset	Name of the CF in EF 3.1
			]azo]naphthalene-2-sulphonic acid, sodium salt
Lignin sulphonates e.g lignosulfonic acid, sodium salt	8061-51-6	This process can be modelled as a mixture of the following: Unbleached kraft pulp, hardwood {WORLD (WITHOUT EU+EFTA+UK, US AND CA)} | technology mix | production mix, at plant | dry mass 0.9, carbon content, non-fossil 0.494 | LCI result + Sodium sulphate production {EU+EFTA+UK} | technology mix | production mix, at plant | 100% active substance | LCI result + Formaldehyde production {EU+EFTA+UK} | technology mix | production mix, at plant | 100% active substance | LCI result	lignosulfonic acid, sodium salt
Benzylbenzoate	120-51-4	This process can be modelled as a mixture of the following: Benzoic acid production {GLO} | technology mix | production mix, at plant | 100% active substance | LCI result + Benzyl alcohol production {EU+EFTA+UK} | technology mix | production mix, at plant | 100% active substance | LCI result	benzyl benzoate
Butylbenzoate	136-60-7	This process can be modelled as a mixture of the following: Butanol production {EU+EFTA+UK} | technology mix | production mix, at plant | 100% active substance | LCI result + Benzoic acid production {GLO} | technology mix | production mix, at plant | 100% active substance | LCI result	n/a
Reactive Blue 72 (phthalocyanine dye)	61968-93-2	Phthalocyanine blue {GLO} | Technology mix | Production mix, at plant | LCI result	n/a
Reactive Black 5 (azo dye belonging to vinyl sulphone type)	17095-24-8	Aniline production {EU+EFTA+UK} | technology mix | production mix, at plant | 100% active substance | LCI result (proxy) no EF and EI dataset available for vinyl sulphone	n/a
Ammonia	7664-41-7	Ammonia {GLO} | global average technology mix | production mix, at plant | 100% active substance | LCI result	ammonia
Hydroxymethyl urea (formaldehyde-rich)	1000-82-4	Urea-formaldehyde resin production {EU+EFTA+UK} | technology mix | production mix, at plant | 100% active substance | LCI result	n/a / however it also generates formaldehyde and methanol emissions
hydroxymethyl melamine (formaldehyde-rich)	*not found*	Melamine methylated {GLO} | Technology mix | Production mix, at plant | LCI result or Melamine formaldehyde resin production {EU+EFTA+UK} | technology mix | production mix, at plant | 100% active substance | LCI result	

Substances	CAS number	EF 3.1 suggested dataset	Name of the CF in EF 3.1
bis(methoxymethyl) melamine (formaldehyde-rich)	*not found;* - possible alternative 1: 3089-11-0 (hexa(methoxymethyl) melamine) - possible alternative 2: 68002-20-0 (methylated melamine-formaldehyde resin, 1,3,5-Triazine-2,4,6-triamine, polymer with formaldehyde, methylated)	Melamine methylated {GLO} | Technology mix | Production mix, at plant | LCI result OR Melamine formaldehyde resin production {EU+EFTA+UK} | technology mix | production mix, at plant | 100% active substance | LCI result	n/a / however it also generates formaldehyde and methanol emissions
Ammonium sulphate	7783-20-2	Ammonium sulfate, per kg n {GLO} | production mix, at plant | 100% N | LCI result	diammonium sulfate
Ammonium nitrate	6484-52-2	Ammonium nitrate, per kg n {GLO} | production mix, at plant | 100% N | LCI result	ammonium nitrate
Ammonium chloride	12125-02-9	Ammonium chloride {EU+EFTA+UK} | technology mix | production mix, at plant | 100% active substance | LCI result	ammonium chloride
[dispersion of] polysiloxanes (e.g. dimethyl polysiloxanes? mentioned for other functions in BREF)	161755-53-9; 9006-65-9 (dimethyl polysiloxanes)	Polysiloxane {GLO} | Technology mix | Production mix, at plant | LCI result	n/a
[dispersion of] polyethylene waxes (partially oxidised polyethylenes)	68441-17-8	no EF dataset and no EcoInvent dataset available	n/a
[dispersion of] polyacrylates (e.g. as in Polymer dispersions (aqueous formulations, 50% water) for Coating (BREF page 869): - poly(meth)acrylate (butyl, ethyl, methyl etc.); - polyacrylic acid; - polyacrylonitrile; - polyacryloamide)	9011-14-7 (Poly(methyl methacrylate)) 9003-63-8 (Poly(butyl methacrylate)) 9003-42-3 (Poly(ethyl methacrylate)) 9003-01-4 (polyacrylic acid) 9009-54-5 (polyurethane) 9003-05-8 (polyacryloamide)	Polyacrylates in water solution production {EU+EFTA+UK} | technology mix | production mix, at plant | 100% active substance | LCI result OR Poly(methyl methacrylate) (PMMA) (acrylic) {GLO} | radical polymerisation of methyl methacrylate (MMA) | production mix, at plant | petrochemical based | LCI result Poly(butyl acrylate) (PBA), petrochemical based {GLO} | esterification of n-butanol and acrylic acid | production mix, at plant | petrochemical based | LCI result Acrylic acid production {EU+EFTA+UK} | technology mix | production mix, at plant | 100% active substance | LCI result Polyacrilonitrile (PAN) {GLO} | polymerisation of acrylonitrile, spinning, post-spinning treatment | production mix, at plant | petrochemical based | LCI result Polyacrylamide production {EU+EFTA+UK} | technology mix | production mix, at plant | 100% active substance | LCI result	n/a

Substances	CAS number	EF 3.1 suggested dataset	Name of the CF in EF 3.1
[dispersion of] polyurethanes (e.g. as in Polymer dispersions (aqueous formulations, 50% water) for Coating (BREF page 869)	9009-54-5	Polyurethane dispersion {EU+EFTA+UK} | Technology mix | Production mix, at plant | Without water | LCI result	n/a
dimethyldioctadecylammonium chloride (cationic softner - fatty acid condensation product)	107-64-2	Non-ionic surfactant, fatty acid derivate production {GLO} | technology mix | production mix, at plant | 100% active substance | LCI result	dimethyldioctadecylammonium chloride
spolyvinyl acetate (e.g. as in Polymer dispersions (aqueous formulations, 50% water) for Coating (BREF page 869)	9003-20-7	Polyvinyl acetate (PVA), fossil fuel-based {GLO} | polymerizing vinyl acetate | production mix, at plant | petrochemical based | LCI result	n/a
Sodium salt dichloroisocyanurate	2893-78-9	Based on Cyanuric chloride {GLO}| cyanuric chloride production | Cut-off, U proxy and modified according to https://www.fao.org/fileadmin/templates/agns/pdf/jecfa/cta/61/NaDCC.pdf	troclosene sodium
Sodium hypochlorite	7681-52-9	Sodium hypochlorite production {EU+EFTA+UK} | technology mix | production mix, at plant | 100% active substance | LCI result	Sodium hypochlorite
sodium bisulphite	7631-90-5	Sodium sulphite production {EU+EFTA+UK} | technology mix | production mix, at plant | 100% active substance | LCI result	sodium hydrogensulfite
Polymer (PA) based resin with epichlorohydrin	*not found (assumed epichlorohydrin as proxy, CAS 106-89-8)*	Modelled from EcoInvent version 3.9.1	epichlorohydrin
Polytetrafluoro ethylene (PTFE)	9002-84-0	Polytetrafluoroethylene (PTFE) {GLO} | suspension polymerisation of tetrafluoroethylene | production mix, at plant | petrochemical based | LCI result	n/a
Benzothiazole derivative (assumed (benzothiazol-2-ylthio)methyl thiocyanate; TCMTB)	21564-17-0	Benzo[thia]diazole-compound production {GLO} | technology mix | production mix, at plant | 100% active substance | LCI result (proxy)	thiocyanic acid (2-benzothiazolylthio)methyl ester

Source: JRC's own elaboration.

Note: 'n/a' means 'not available'. '(proxy)' in brackets indicates that the dataset is not exactly representing exactly the substance under assessment, but mainly a parent-compound.

6.5 Main life cycle inventory tables

Table 65. Life cycle stages for the Base Case.

Products	Value	Unit	Comment
Life cycle of the Base Case	500	g	The weight of the Base Case is 0.5 kg.
Electricity/heat			
LCS1- Agricultural phase	500	g	Agricultural phase (for wool, cashmere and cotton) of the Raw material supply and pre-processing stage
LCS1 - Fibres production phase	500	g	Man-made fibres production of the Raw material supply and pre-processing stage
LCS2 – Manufacturing stage	500	g	The manufacturing includes the steps reported in **Table 66**
LCS3 – Distribution stage	500	g	For this report, the datasets and values used in the distribution stage cannot be reported for confidentiality reasons
LCS4 – Use stage	500	g	The use stage is detailed in **Table 67**
LCS5 - End of life stage	500	g	The end-of-life stage is detailed in **Table 68**

Source: JRC's own elaboration.

Table 66. Life cycle inventory for the Life cycle stage 2 - Manufacturing of the Base Case.

Products		Value	Unit	Comment
Life cycle stage 2 - Manufacturing Base Case		500	g	The weight of the Base Case is 0.5 kg. All energies and resources consumption for all the manufacturing steps are reported separately from substances used in the steps, to ease the identification of substances when performing the life cycle impact assessment.
Resources				
Water, well	in water	~6E-2	m^3	Water consumption elaborated from Ecoinvent version 3.9.1.
Water, well	in water	~2E-1	m^3	Water consumption elaborated from Ecoinvent version 3.9.1.
Materials/fuels				
Tap water {GLO} | average technology mix | consumption mix, at consumer | Technology mix for supply of drinking water to users | LCI result		~8	l	Water consumption elaborated from Ecoinvent version 3.9.1.
Tap water {GLO} | average technology mix | consumption mix, at consumer | Technology mix for supply of drinking water to users | LCI result		0.011	m^3	The specific water consumption for scouring ranges from 1 m^3/t to 43 m^3/t (source BREF). Average value assumed
Electricity/heat				
Scouring (input substances and emissions only)		500	g	Input substances needed to manufacture the Base Case. Corresponding emissions are reported, if the characterization factor (CF) in EF 3.1 was available. The detail of the datasets used for input substances and the availability of CFs is reported in **Table 64** and the quantification is reported in **Table 29.**

Products	Value	Unit	Comment
Yarn and fabric production (input substances and emissions only)	500	g	Input substances needed to manufacture the Base Case. Corresponding emissions are reported, if the characterization factor (CF) in EF 3.1 was available. The detail of the datasets used for input substances and the availability of CFs is reported in **Table 64** and the quantification is reported in **Table 29.**
Washing (input substances and emissions only)	500	g	Input substances needed to manufacture the Base Case. Corresponding emissions are reported, if the characterization factor (CF) in EF 3.1 was available. The detail of the datasets used for input substances and the availability of CFs is reported in **Table 64** and the quantification is reported in **Table 29.**
Bleaching (cotton) (input substances and emissions only)	500	g	Input substances needed to manufacture the Base Case. Corresponding emissions are reported, if the characterization factor (CF) in EF 3.1 was available. The detail of the datasets used for input substances and the availability of CFs is reported in **Table 64** and the quantification is reported in **Table 29.**
Bleaching (wool and cashmere) (input substances and emissions only)	500	g	Input substances needed to manufacture the Base Case. Corresponding emissions are reported, if the characterization factor (CF) in EF 3.1 was available. The detail of the datasets used for input substances and the availability of CFs is reported in **Table 64** and the quantification is reported in **Table 29.**
Dyeing (input substances and emissions only)	500	g	Input substances needed to manufacture the Base Case. Corresponding emissions are reported, if the characterization factor (CF) in EF 3.1 was available. The detail of the datasets used for input substances and the availability of CFs is reported in **Table 64** and the quantification is reported in **Table 29.**
Finishing (input substances and emissions only)	500	g	Input substances needed to manufacture the Base Case. Corresponding emissions are reported, if the characterization factor (CF) in EF 3.1 was available. The detail of the datasets used for input substances and the availability of CFs is reported in **Table 64** and the quantification is reported in **Table 29.**
Drying (input substances and emissions only)	500	g	Input substances needed to manufacture the Base Case. Corresponding emissions are reported, if the characterization factor (CF) in EF 3.1 was available. The detail of the datasets used for input substances and the availability of CFs is reported in **Table 64** and the quantification is reported in **Table 29.**
Thermal energy from natural gas {RoW} | technology mix regarding firing and flue gas cleaning | production mix, at heat plant | MJ, 100% efficiency | LCI result	3.3	kWh	The specific energy consumption for scouring ranges from 65.7 kWh/t to 13 117 kWh/t. (source BREF textiles). From Figure 3.95 we can see that the highest contribution of the upper limit is heat. Average value assumed.
Electricity grid mix 1kV-60kV {EU+EFTA+UK} | technology mix | consumption mix, to consumer | 1kV - 60kV | LCI result	~3	kWh	Energy consumption elaborated from Ecoinvent version 3.9.1.
Electricity grid mix 1kV-60kV {EU+EFTA+UK} | technology mix | consumption mix, to consumer | 1kV - 60kV | LCI result	~4	kWh	Energy consumption elaborated from Ecoinvent version 3.9.1.
Electricity grid mix 1kV-60kV {EU+EFTA+UK} | technology mix | consumption mix, to consumer | 1kV - 60kV | LCI result	~5E-1	kWh	Energy consumption elaborated from Ecoinvent version 3.9.1.
Electricity grid mix 1kV-60kV {EU+EFTA+UK} | technology mix | consumption mix, to consumer | 1kV - 60kV | LCI result	~4E-1	kWh	Energy consumption elaborated from Ecoinvent version 3.9.1.
Thermal energy from natural gas {RoW} | technology mix regarding firing and flue gas cleaning | production mix, at heat plant | MJ, 100% efficiency | LCI result	~3E-1	MJ	Energy consumption elaborated from Ecoinvent version 3.9.1.
Process steam from natural gas {RoW} | technology mix regarding firing and flue gas cleaning | production mix, at heat plant | MJ, 90% efficiency | LCI result	~130	MJ	Energy consumption elaborated from Ecoinvent version 3.9.1.
Electricity grid mix 1kV-60kV {EU+EFTA+UK} | technology mix | consumption mix, to consumer | 1kV - 60kV | LCI result	~2E-1	kWh	Energy consumption elaborated from Ecoinvent version 3.9.1.
Thermal energy from natural gas {RoW} | technology mix regarding firing and flue gas cleaning | production mix, at heat plant | MJ, 100% efficiency | LCI result	~5	MJ	Energy consumption elaborated from Ecoinvent version 3.9.1.

Products	Value	Unit	Comment
Thermal energy from hard coal {RoW} | technology mix regarding firing and flue gas cleaning | production mix, at heat plant | MJ, 100% efficiency | LCI result	~2	MJ	Energy consumption elaborated from Ecoinvent version 3.9.1.
Emissions to air			
Particulates, > 10 um high. pop.	~1E-1	kg	Emissions elaborated from Ecoinvent version 3.9.1.
Waste to treatment			
Landfill of textile {EU+EFTA+UK} | landfill including leachate treatment and with transport without collection and pre-treatment | production mix (region specific sites), at landfill site | The carbon and water content are respectively of 40%C and and 12% Water (in weight %) | LCI result	~2E-1	kg	Treatment of textile waste elaborated from Ecoinvent version 3.9.1.
Landfill of textile {EU+EFTA+UK} | landfill including leachate treatment and with transport without collection and pre-treatment | production mix (region specific sites), at landfill site | The carbon and water content are respectively of 40%C and and 12% Water (in weight %) | LCI result	~5E-2	kg	Treatment of textile waste elaborated from Ecoinvent version 3.9.1.
Waste incineration of hazardous waste {EU+EFTA+UK} | waste-to-energy plant with dry flue gas treatment, including transport and pre-treatment | production mix, at consumer | hazardous waste | LCI result	~1E-3	kg	Treatment of waste oil elaborated from Ecoinvent version 3.9.1.
Treatment of residential wastewater, large plant {EU+EFTA+UK} | wastewater treatment including sludge treatment | production mix, at plant | 1m3 of wastewater treated | LCI result	~80	kg	Wastewater treatment elaborated from Ecoinvent version 3.9.1.

Source: JRC's own elaboration.

Table 67. Life cycle inventory for the Life cycle stage 4 - Use of the Base Case.

Products	Value	Unit	Comment
Life cycle stage 4 - Use Base Case	500	g	The weight of the Base Case is 0.5 kg. Resource and energies consumption elaborated from EcoInvent version 3.9.1.
Materials/fuels			
Non-ionic surfactant, fatty acid derivate production {GLO} | technology mix | production mix, at plant | 100% active substance | LCI result	~0.1	kg	Non-ionic surfactant consumption elaborated from EcoInvent version 3.9.1.
Tap water {GLO} | average technology mix | consumption mix, at consumer | Technology mix for supply of drinking water to users | LCI result	~100	l	Water consumption elaborated from EcoInvent version 3.9.1.
Electricity/heat			
Electricity grid mix 1kV-60kV {EU+EFTA+UK} | technology mix | consumption mix, to consumer | 1kV - 60kV | LCI result	~1.3	kWh	Energy consumption elaborated from EcoInvent version 3.9.1.
Thermal energy from natural gas {EU+EFTA+UK} | technology mix regarding firing and flue gas cleaning | production mix, at heat plant | MJ, 100% efficiency | LCI result	~30	MJ	Energy consumption elaborated from EcoInvent version 3.9.1.
Use (emissions only)	500	g	Emissions deriving during use stage from substances included in the manufacturing

Products		Value	Unit	Comment
Emissions to air				
Water/m3	high. pop.	~4E-3	m^3	Water emission elaborated from EcoInvent version 3.9.1.
Waste to treatment				
Treatment of residential wastewater, small plant {EU+EFTA+UK} | wastewater treatment including sludge treatment | production mix, at plant | 1m3 of wastewater treated | LCI result		~0.11	ton	Wastewater treatment elaborated from EcoInvent version 3.9.1.

Source: JRC's own elaboration.

Table 68. Life cycle inventory for the Life cycle stage 5 - End of life of the Base Case

Products	Value	Unit	Comment
Life cycle stage 5 - End of life	500	g	The weight of the Base Case is 0.5 kg. The end of life considers the shares of the end of life treatments
Electricity/heat			
Landfilling (emissions only)	500	g	The emissions in landfilling have been quantified in **Table 38**.
Incineration (emissions only)	500	g	The emissions in incineration have been quantified in **Table 40**.
Waste to treatment			
Landfill of textile {EU+EFTA+UK} | landfill including leachate treatment and with transport without collection and pre-treatment | production mix (region specific sites), at landfill site | The carbon and water content are respectively of 40%C and and 12% Water (in weight %) | LCI result	~48	%	For confidentiality reasons, the shares of the post-consumer waste at the end of life have been reported (as in **Table 34**).
Waste incineration of textile, animal and plant based {EU+EFTA+UK} | waste-to-energy plant with dry flue gas treatment, including transport and pre-treatment | production mix, at consumer | textile waste | LCI result	~13.17	%	For confidentiality reasons, the shares of the post-consumer waste at the end of life have been reported (as in **Table 34**).
Waste incineration of PET {EU+EFTA+UK} | waste-to-energy plant with dry flue gas treatment, including transport and pre-treatment | production mix, at consumer | polyethylene terephthalate waste | LCI result	~13.17	%	For confidentiality reasons, the shares of the post-consumer waste at the end of life have been reported (as in **Table 34**).
Waste incineration of inert material {EU+EFTA+UK} | waste-to-energy plant with dry flue gas treatment, including transport and pre-treatment | production mix, at consumer | inert material waste | LCI result	~13.17	%	For confidentiality reasons, the shares of the post-consumer waste at the end of life have been reported (as in **Table 34**).
Recycling, downcycling {GLO} | collection, sorting, transport, washing, granulation, pelletization | production mix, at plant | 61.9% recycling rate (synthetic textiles), 38.2 % recycling rate (natural textiles) | LCI result	~7	%	For confidentiality reasons, the shares of the post-consumer waste at the end of life have been reported (as in **Table 34**).

Source: JRC's own elaboration.

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