ZeroPM

Zero pollution of Persistent, Mobile substances

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Lessons learned from previous applications of the essential use concept

Work Package 2 – Alternatives assessment

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Stockholm University

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Note about contributors

Lead partner responsible for the deliverable:	Stockholm University (SU)
Deliverable prepared by:	Romain Figuière Ian Cousins
Partner responsible for quality control:	Deutscher Verein des Gas und Wasserfaches – Technisch-Wissentschaftlicher Verein EV (DVGW); Norwegian Geotechnical Institute (NGI)
Deliverable reviewed by:	Sarah Hale; Hans Peter H. Arp
Other contributors:	Zhanyun Wang (EMPA)

Project information

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Web-site:	www.zeropm.eu
Project coordinator:	Norwegian Geotechnical Institute, (NGI project no.: 20210423)

Project partners:

Summary

The goal of the deliverable is to evaluate whether substantial changes are needed in present chemical regulations in order to implement the essential-use concept to guide regulatory decision-making. The evaluation focuses on the Stockholm Convention and the EU REACH Regulation as they are the two chemical regulations with the broadest scope in terms of chemical uses, and are both relevant chemicals regulations for members and associate members of the European Union. To determine if these current chemicals regulations required major modifications to implement the essential-use concept, a detailed analysis of the regulations was first conducted. Then, an analysis was conducted of 1) previous restrictions under REACH, 2) previous applications for authorisations under REACH, and 3) exemptions granted under the Stockholm Convention. A focus of this analysis is to scrutinize use cases where hazardous substances have been granted. A key consideration is how derogations from previous restrictions, as well as decisions on granted authorisations under REACH, differ from the essential-use concept components. Finally, the essential-use concept was applied to the intentionally added microplastics restriction dossier to assess how an implementation of the concept may have influenced outcomes. This deliverable concludes that no major changes in the current chemical regulations are necessary to implement the essential-use concept as a tool to guide authorisations and restrictions under REACH and even exemptions under the Stockholm Convention. Challenges remain, however, for its implementation. Authorities require a thorough understanding of the uses of the chemicals of concern, their supply chains, and the availability of potential alternatives. This deliverable is a further output of task 2.2 and will feed into task 3.3 of ZeroPM.

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1 Introduction

ZeroPM, which stands for Zero pollution of Persistent, Mobile substances, is a 5 year long European research project funded under the Horizon 2020 research and innovation program. ZeroPM will interlink and synergize three strategies to protect the environment and human health from persistent and mobile (PM) substances: Prevent, Prioritize and Remove. To do this, ZeroPM will develop an evidence-based multilevel framework. The framework will guide policy, technological and market incentives to minimize use, emissions and pollution of entire groups of PM substances. WP2 in ZeroPM is focused on Alternatives Assessment, where its main goal is to provide safer chemical alternatives to non-essential uses of prioritized persistent and mobile substances.

The "essential use concept" was first introduced in the Montreal Protocol as a tool to guide the phase out of uses of ozone layer depleting substances[1]. In their decision, the Parties agreed that all uses of these substances should be restricted except where they would be deemed essential for society, and that a "controlled substance should qualify as 'essential' only if: (1) it is necessary for the health, safety or is critical for the functioning of society (encompassing cultural and intellectual aspects); and (2) there are no available technically and economically feasible alternatives or substitutes that are acceptable from the standpoint of the environment and health"[1,2]. More recently, Cousins et al. suggested applying this concept to guide the phase out of uses of per- and polyfluoroalkyl substances (PFAS)[3]. Furthermore, the European Commission proposed implementing the concept in chemicals policy based on the Chemicals Strategy for Sustainability towards a Toxic Free Environment (CSS), in order to guide decision-making on potential derogations from future restrictions[4]. In this manner, the CSS aims to apply the concept to a much broader scope of uses of chemical substances than within the Montreal Protocol, which can make its implementation both more impactful and challenging. There are some different ideas, as well as confusion, about how the essential-use concept should be applied to chemical substances and reflecting this debate ZeroPM wrote a document summarizing some of the key concepts[5].

In April 2023, a study commissioned by the European Commission proposed a framework and defined a set of criteria to implement the essential-use concept in EU chemical regulations based on several interviews with various stakeholders[6]. In this framework, the authors suggested to divide the assessment of essential-use into three main steps:

- **Scoping of the assessment**: First the assessor should determine whether the substance of concern is considered as a "most harmful chemical" as defined in the CSS (which referred to "substances that cause cancers, gene mutations, affect the reproductive or the endocrine system, or are persistent and bioaccumulative"[4], or based on how they are used could affecting the "immune, neurological or respiratory systems and chemicals toxic to a specific organ"[4]);, and they should define the use of the substance by "considering the societal need for the technical function provided by the most harmful chemical in a specific end use (e.g. final product) in a defined setting";
- **Assessment of criticality and necessity**: then, the assessor should evaluate whether the use of the substance of concern is necessary for health and/or safety, and whether it is critical for the functioning of society;

- **Alternatives assessment**: finally, the assessor should determine whether suitable alternatives that are acceptable from the standpoint of the environment and human health are available "for society as a whole, not only for the applicant".

Following this framework, a use of a chemical substance can be considered as "essential" only if the assessment reveals that it is necessary for health and/or safety; OR that it is critical for the functioning of society; AND that there no acceptable alternatives available. The conclusion on the essentiality of a use should "expire after the time period set for authorisation/derogation", after which "the use may be reassessed for essentiality, or, the authorisation/derogation expires and the use ceases[6].

The goal of the present deliverable is to evaluate whether substantial changes are needed in current European chemical regulations in order to implement the essential-use concept as defined above to guide decision-making. The evaluation focuses on the implementation of the concept in the Stockholm Convention and the EU REACH Regulation as they are the two chemical regulations with the broadest scope in terms of chemical uses (in contrast to use specific regulations like biocides, pharmaceuticals, etc.), and are both relevant chemicals regulations for members and associate members of the European Union. When a substance is restricted under the Stockholm Convention, the Conference of the Parties can grant exemptions for specific uses of the substance which can be continued after the restriction enter into force[7]. Similarly, under the EU REACH Restriction process, the European Commission can grant specific derogations for uses of the substance of concern for which the restriction will not be applied[8]. Under the EU REACH Authorisation process, the European Commission can grant authorisation to companies for them to continue using substances of very high concern (SVHC) for a limited period of time[9]. The deliverable analyses how decisions on derogations from previous restrictions, as well as decisions on granted authorisations under REACH differ from the essential-use concept components, and then evaluates whether the essential-use concept could be implemented in the current state of REACH. The deliverable further evaluates the previous exemptions granted under the Stockholm Convention and determines where exemptions were granted for reasons which can relate to the essential-use concept. General information on the methods are provided as well as the main findings. The full details are provided in the annexes, which comprise published or draft research articles in preparation as part of the ZeroPM research project.

2 Background information on chemical regulations

2.1 Stockholm Convention

Adopted in 2001, the Stockholm Convention is a global treaty that aims to protect human health and the environment from persistent organic pollutants (POP), i.e. chemicals which "remain intact for exceptionally long period, become widely distributed throughout the environment as a result of natural processes involving soil, water and, most notably, air, accumulate in living organisms including humans, […] and are toxic to both humans and wildlife"[10]. As of February 2024, 186 Parties are members of the Stockholm Convention. Among other provisions, each Party is required to:

- Prohibit and eliminate the production and use of the substances listed in Annex A;
- Restrict the production and use of the substances listed in Annex B; and
- Reduce and eliminate releases of unintentionally produced substances listed in Annex C.

At its adoption, 9 substances were listed in Annex A for elimination, 1 substance was listed in Annex B for restriction, and 4 substances were listed in Annex C for reduction of releases[7]. A Party has the possibility to nominate a substance to be listed in one of the annexes. Such a nomination triggers a three-step scientific assessment by the POPs Review Committee (POPRC):

- A screening of the properties of the substance of concern compared to the POP criteria listed in Annex D of the Convention;
- An assessment of the substances risk profile considering hazard and exposure in accordance with Annex E of the Convention; and
- A risk management evaluation which assesses social-economic aspects in accordance with Annex F of the Convention.

Based on those assessments, the POPRC makes recommendations on the potential listing (or not) of the substance on the annexes A, B or C to the Conference of Parties (COP), the Convention's governance body. The COP makes the final decisions on the listing of the substance of concern, including potential exemptions for specific uses. Once listed and ratified, Parties are obliged to eliminate or restrict the uses of the substance of concern listed in the annexes A and B, respectively, except for the potential exemptions.[7] As of November 2023, 34 chemicals or groups of chemicals are listed under the Convention in the different annexes (30 substances are listed in the Annex A; 2 in the Annex B; and 7 in the annex C), and 4 more are under evaluation or ready for decisions by the COP[11].

2.2 Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (EC 1907/2006)

The REACH Regulation, which entered into force in 2007, is a European-wide regulation on chemicals which aims to improve the protection of human health and the environment from the risks that can be posed by chemicals, while enhancing the competitiveness of the European Union chemical industry. In principle, the REACH Regulation applies to all types of chemical substances used in industrial settings and consumer products, with the exception of specific uses under existing regulations (e.g. biocides, plant protection products, pharmaceuticals, etc.). To comply with the regulation, companies must identify and manage the risk posed by the chemical substances they manufacture and place on the EU market. They must prove to the European Chemicals Agency (ECHA) that their substances can be safely handled[12].

If the risks posed by a chemical substance cannot be adequately managed, the authorities have the possibility to restrict and/or ban its uses via two main processes: the Restriction and the Authorisation processes.

The REACH Restriction process

Restrictions under REACH can limit or ban the uses of a chemical substance which pose unacceptable risks to human health and/or the environment. A restriction can be applied to any substance on its own, in a mixture or in an article[8]. The process can be started by one (or several) Member States, or by ECHA, on request of the European Commission. The intention for proposing a restriction is made public in the registry of intentions to give an advance warning to the affected stakeholders.

The restriction dossier contains background information on the identity of the substance of concern and justifications for the proposed restriction. It includes a description of the risks posed by the uses of the substances, any information available on potential alternatives and the costs and benefits for society resulting from the restriction. The dossier submitter must file such a dossier within 12 months once the intention is made public[8].

The restriction dossier is then evaluated by the risk assessment committee (RAC), and the socio-economic assessment committee (SEAC). RAC provides its opinion on whether the suggested restriction is appropriate to reduce the risks linked to the uses of the substance of concern, while SEAC prepares an opinion on the socio-economic impacts of the suggested restriction, including potential derogations to the restriction.

The European Commission takes the final decision on the proposed restriction, including on potential derogations, based on the final opinions of RAC and SEAC. If adopted, the restriction is listed in Annex XVII of REACH[8].

As of November 2023, 65 intentions of restrictions were made since REACH entered into force. The Annex XVII of REACH includes all restrictions adopted under REACH and the previous legislation (Directive 76/769/EEC). A total of 78 entries have been made to the Annex XVII, covering 2127 different substances[13].

The REACH Authorisation process

The Authorisation process aims to protect human health and the environment from substances of very high concern (SVHC) by encouraging their progressive replacement by less dangerous substances or technologies[12]. The process can be started by a Member State or ECHA, on request of the European Commission, by proposing a substance to be identified as a SVHC. A substance is identified as a SVHC if it meets the criteria for classification as carcinogenic, mutagenic or toxic for reproduction (CMR) category 1A or 1B under the CLP Regulation; it is persistent, bioaccumulative, and toxic (PBT), or very persistent and very bioaccumulative (vPvB) according to the Annex XIII of REACH; or if poses an equivalent level of concern as CMR, PBT or vPvB substances. Once identified as a SVHC, the substance is listed in the Candidate List[14].

ECHA regularly assesses the substances listed in the Candidate List to determine which one should be prioritised to be included in the Authorisation List. The prioritisation is based on information on the intrinsic properties, wide dispersive use or high volume used of the substance of concern. The Member State Committee prepares its opinion on ECHA's recommendation for inclusion on the Authorisation List. The European Commission takes the final decision on the substance to be included in the Authorisation List based on ECHA final recommendations[15].

Once a substance is included in the Authorisation List, the European Commission sets a so called "sunset date", after which any uses of the substance of concern in the EU are prohibited. If a company wishes to continue or to start using a substance listed in the Authorisation List after its sunset date, they must submit an application for authorisation (AfA) to ECHA. In an AfA, the applicant must demonstrate (1a) that the risk linked to its use of the SVHC is adequately controlled (so-called "Adequate control route"); or (1b) that the socio-economic benefits resulting from its use of the SVHC outweigh the risks linked to its use of the SVHC (so-called "SEA route"); and (2) that there are no suitable alternatives which are available for its particular use. RAC and SEAC evaluate the AfA and issue their opinions on whether a time-limited authorisation to keep using a SVHC for their specific use should be granted to the applicant based on the information provided. The European Commission takes the final decision to grant an authorisation based on the final opinions of RAC and SEAC, including the length of such an authorisation[9].

As of November 2023, 476 substances have been identified as SVHCs, while 59 entries covering 141 substances have been made to the Authorisation List[16].

3 Methods

3.1 Analysis of the reasoning for granting derogations and exemptions from existing restrictions

Opinions of the POPRC and SEAC on previous restrictions and final decisions of the COP and the European Commission under the Stockholm Convention and REACH Regulation were analysed following the READ approach ((1) readying the materials, (2) extraction of the data, (3) analysis of the data and (4) distilling the findings) to determine whether the reasoning for granting a derogation could relate to one of the essential-use components[17]. Table 3-1 provides an overview of the approach and the full method details are provided in **Annex A**.

Given the high number of AfA at the time of the study (*n = 448*)[18], it was not feasible to analyse all SEAC final opinions. Instead, the REACH legal text related to the Authorisation process was analysed to determine the legal basis for a company to obtain an authorisation following the READ approach. Table 3-1 provides an overview of the approach, and full method details are provided in **Annex B**.

Table 3-1 Summary of the READ method followed for the analysis of policy documents

Regulation	Step 1: Readying the material	Step 2: Extraction of the data	Step 3: Analysis of the data	Step 4: Distilling the findings	For more information
Stockholm Convention	POPRC Risk management evaluation on previous listing (*n = 22*) Decision of the COP (*n = 22*)	Information on rational of POPRC for recommending exemptions, and final decision by COP.	Exemptions grouped into 4 categories based on the main reason for recommending it: (1) Use if critical for health, safety or functioning of society; (2) no alternatives are available for the use; (3) actors of the specific use need more time to transition towards an alternative; and (4) other reasons.	The data were analysed to determine how the outcomes of the Stockholm Convention match or differ from the essential-use concept.	**Annex A**
REACH Regulation – Restriction process	SEAC final opinions on previous restriction proposal (*n = 45*) Legal decision of the European Commission (*n = 29*)	Information on rational of SEAC for recommending derogations, and final decision by the European Commission.	Derogations grouped into 4 categories based on the main reason for recommending it: (1) Use if critical for health, safety or functioning of society; (2) no alternatives are available for the use; (3) actors of the specific use need more time to transition towards an alternative; and (4) other reasons.	The data were analysed to determine how the outcomes of the Restriction process under REACH match or differ from the essential-use concept.	**Annex A**
REACH Regulation – Authorisation process	Title VII of the REACH Regulation (EC No 1907/2006) Annex XVI of the REACH Regulation (EC No 1907/2006)	Legal obligations related to applications for authorisation for companies and the European Commission	Legal requirements for a company to apply for authorisation; Legal requirements for the European Commission to grant (or refuse) an authorisation.	To determine whether the European Commission could grant (or refuse) an authorisation based on the essentiality of the use applied for; To determine what information companies are obliged to provide.	**Annex B**

3.2 Applicability of the essential-use concept in the current state of chemical regulations

REACH Restrictions

The restriction dossier on intentionally added microplastics served as a case study to determine whether the essential-use concept could have been applied at the time of the restriction to guide decision-making on potential derogations from the restriction[19]. An assessment of essentiality of the uses of microplastics discussed in the background document of the restriction was performed following the framework proposed by the consultancy firm WSP, in a report commissioned by the European Commission[6]. The exact method followed for the assessment is detailed in **Annex A**.

REACH Authorisation

First, the guidance documents for companies on how to prepare an AfA were analysed following the READ approach to determine whether the information companies should provide when seeking an authorisation is enough for the authorities to determine if the use applied for can be considered as essential[20]. Then, a pool of 100 past AfA which include a substitution plan and for which the SEAC final opinion has been published were analysed to determine if SEAC and the European Commission could have concluded on the essentiality of the uses applied for based on the information actually provided by the companies at the time of their application by following the framework proposed by WSP[6,18]. The exact methods followed for these assessments are detailed in **Annexes B** and **C**, respectively.

Stockholm Convention

To the best of our knowledge, it is not possible to access the background information that supports the POPRC risk management evaluation. It was therefore not possible to make a similar assessment on whether the essential-use concept could be applied in the current state of this regulation.

4 Results

4.1 Analysis of the reasoning for granting derogations and exemptions from existing restrictions

Figure 4-1 provides an overview of the results. The following text presents the main findings and conclusions of the deliverable. The more detailed and complete results are available in **Annexes A** and **B**.

Stockholm Convention

Under the Stockholm Convention, the majority of the exemptions were granted for uses for which alternatives were lacking at the time of the decision, which can relate to the essential-use concept. However, no exemptions were granted due to the criticality of the use for health, safety or the functioning of society (**Figure 4-1 C**). 9% of the exemptions were granted for other reasons, mainly due to the complexity of implementing the restriction for those specific uses (e.g. the exemption for recycling materials containing PBDEs as impurities).

REACH Restriction process

The REACH Restriction process presents the most discrepancies with the essential-use concept in the reasoning for granting derogations. 63% of the derogations were recommended by SEAC for other reasons than the essential-use components (**Figure 4-1 A**). However, the majority of these derogations were recommended for technical reasons specific to the REACH Restriction process (e.g. because the specific use falls outside of the scope of the restriction dossier; because the specific use is regulated elsewhere etc.). In those cases, it is unlikely that the essential-use concept would have influenced the outcome of the decision-making if it was applied at the time. On the other hand, 17% of the derogations were recommended because it was believed that the exposure and/or risks resulting from the specific use was negligible, or because the costs of restricting the use outweighed the benefits (**Figure 4-1 A**). If the essential-use concept was implemented at the time, it is unlikely that such derogations would be granted as the discussions regarding the derogations would have been focused on the essentiality of the specific uses for society instead of the risks resulting from it.

Hence, it can be concluded that the essential-use concept could have influenced the outcome of the decision-making on less than 20% of the previous derogations recommended in the REACH Restriction process.

REACH Authorisation process

The analysis of the legal text that defines the Authorisation process under REACH revealed that a company that seeks an authorisation must prove that (1a) the risk linked to its use of the substance of concern is adequately controlled (so called "adequate control route"), or (1b) that the costs of ceasing its use of the substance outweigh the benefits (so called "SEA route"); and (2) that there are no suitable alternative for its use of the substance of concern. Therefore, it has been considered that all were granted for reasons which could relate to one aspect of the essential-use component, i.e. the availability of alternatives. However, a quick analysis of the SEAC final opinions on previous AfA showed that 4% of the AfA followed the "adequate control route" (**Figure 4-1 B**), for which the essential-use concept could not have influenced the outcome of the decision-making due to legal constraints (**Annex B**). Furthermore, an analysis of an overview table on the availability of alternatives to applicants prepared by ECHA allowed to differentiate cases in which companies have identified a promising alternative but need more time to fully implement it in their process, from cases in which companies have not identified potential alternatives at the time of their applications (**Figure 4-1 B**).

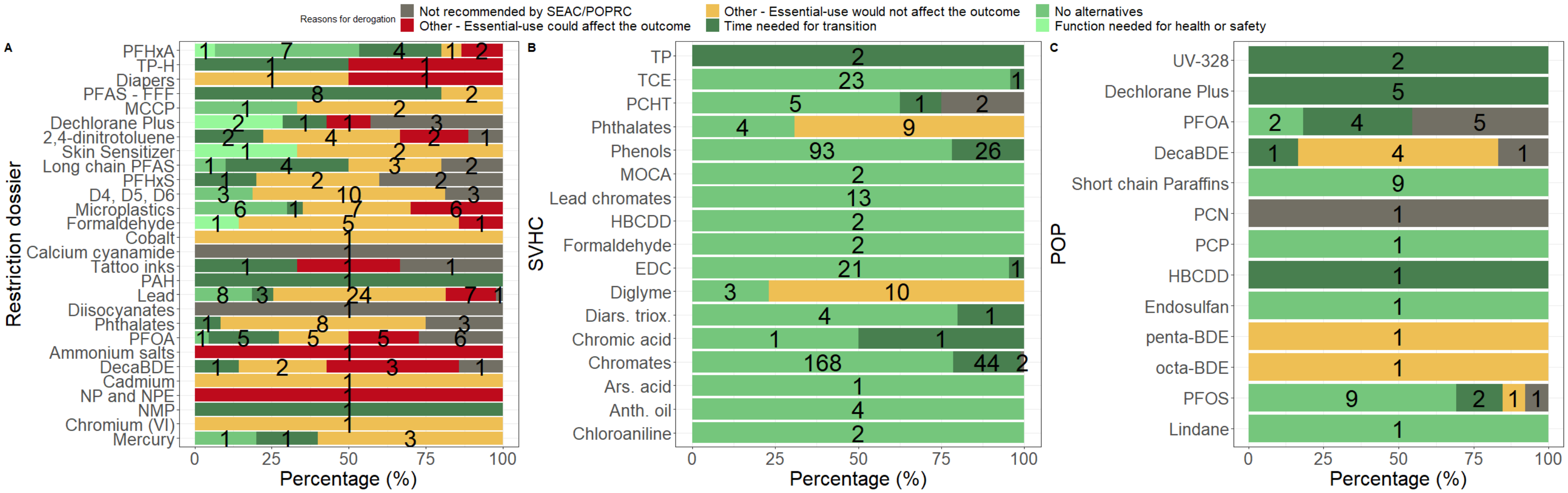

Figure 4-1 Reasons for derogations in former REACH restriction dossiers (A), applications for authorisation under REACH (B), and substances listed under the Stockholm Convention (C)

Note: To facilitate the reading of the figures, numbers of several restriction dossiers, and numbers for applications for authorisation for the continued uses of several SVHC were aggregated as follow:

(A) "Lead" represents an aggregation of the data related to 5 different restriction dossiers (i.e., lead in projectiles (for firearms and air guns), and in fishing sinkers and lures for outdoor activities; lead and its compounds in shots for shooting in wetlands; lead and its compounds as PVC stabilizer; lead and its compounds in consumer articles; and lead and its compounds in jewelry);

(B) "Phthalates" represents an aggregation of the data related to bis(2-ethylhexyl) phthalate and dibutyl phthalate; "Phenols" represents an aggregation of the data related to 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated, and 4-nonylphenol, branched and linear, ethoxylated; "Lead chromates" represents an aggregation of the data related to lead chromate, lead chromate molybdate sulphate red (C.I. pigment red 104), and lead sulfochromate yellow (C.I. pigment yellow 34); "Chromates" represents an aggregation of the data related to ammonium dichromate, chromium trioxide, dichromium tris(chromate), pentazinc chromate octahydroxide, potassium chromate, potassium dichromate, potassium hydroxyoctaoxodizincatedichromate, sodium chromate, sodium dichromate, and strontium chromate.

Abbreviations:

(A) NMP: 1-methyl-2-pyrrolidone; NP and NPE: 4-nonylphenol, branched and linear, and 4-nonylphenol, branched and linear, ethoxylated; DecaBDE: Bis(pentabromophenyl) ether; Ammonium salts: inorganic ammonium salts; PFOA: perfluorooctanoic acid, its salts and PFOA-related substances; Phthalates: diisobutyl phthalate, dibutyl phthalate, benzyl butyl phthalate, and bis(2-ethylhexyl) phthalate; PAH: Polycyclic-aromatic hydrocarbons; Tattoo inks: substances in tattoo inks and permanent make-up; Cobalt: cobalt carbonate, cobalt di(acetate), cobalt dichloride, cobalt dinitrate, and cobalt sulphate; Formaldehyde;: formaldehyde and formaldehyde releasers; Microplastics: intentionally added microplastics; D4, D5, D6: octamethylcyclotetrasiloxane, decamethylcyclopentasiloxane, and dodecamethylcyclohexasiloxane; PFHxS: perfluorohexane-1-sulphonic acid, its salts and related substances; Long chain PFAS: perfluorononan-1-oic acid (PFNA), nonadecafluorodecanoic acid (PFDA), henicosafluoroundecanoic acid (PFUnDA), tricosafluorododecanoic acid (PFDoDA), pentacosafluorotridecanoic acid (PFTrDA), heptacosafluorotetradecanoic acid (PFTDA), including their salts and precursors; Skin Sensitizer: Skin sensitizing , irritative and/or corrosive substances; Dechlorane Plus: 1,6,7,8,9,14,15,16,17,17,18,18-Dodecachloropentacyclo[12.2.1.16,9.02,13.05,10]octadeca-7,15-diene; MCCP: medium-chain chlorinated paraffins; PFAS – FFF: per- and polyfluoroalkyl substances in firefighting foams; Diapers: Substances in single-use baby diapers; TP-H: terphenyl, hydrogenated; PFHxA: undecafluorohexanoic acid, its salts and related substances;

(B) Chloroaniline: 4,4'-methylenebis[2-chloroaniline]; Anth. Oil: Anthracen oil; Ars. acid: Arsenic acid; Diars. triox.: diarsenic trioxide; Diglyme: bis(2-methoxyethyl) ether; EDC: 1,2-dichloroethane; formaldehyde: formaldehyde, oligomeric reaction products with aniline; HBCDD: hexabromocyclododecane, alpha-hexabromocyclododecane; beta-hexabromocyclododecane, gamma-hexabromocyclododecane; MOCA: 2,2'-dichloro-4,4'-methyelenedianiline; PCHT: pitch, coal tar, high temperature; TCE: trichloroethylene; TP: trixylyl phosphate;

(C) PFOS: perfluorooctane sulfonate; octa-BDE: commercial octabromodiphenyl ether (its components: hexabromodipenyl & heptabromodihenyl); penta-BDE: commercial pentabromodiphenyl ether (ist components tetra- & hexabromodiphenyl ether); HBCDD: hexabromocyclododecane; PCP: pentachlorophenol and its salts and esthers; PCN: chlorinated naphthalenes

4.2 Applicability of the essential-use concept in the current state of chemical regulations – a case-study on intentionally added microplastics

REACH Restriction

The following presents the main conclusion from the case study on the restriction dossier on intentionally added microplastics. The detailed analysis of the case study is provided in **Annex A**. Based on the analysis, the outcomes of decision-making would have been the same by following the essential-use concept for 13 derogations out of the 20 which have been recommended by SEAC at the time of the restriction. For the uses of microplastics in rinse-off cosmetic products, fragrance encapsulates and leave on cosmetic products, it was concluded that derogations would not have been recommended following the essential-use concept as it was believed that the functions delivered by microplastics in those applications were not necessary for health and safety nor critical for the functioning of society according to the criteria proposed by WSP.

It was also concluded that derogations for applications where microplastics are contained by technical means to prevent releases, where the physical properties of microplastics are permanently modified, or where microplastics are permanently incorporated in a solid matrix would not have been discussed if the essential-use concept would have been applied at the time. In those cases, the focus of the discussion would have been on the purposes of the applications, and not on whether microplastics could be released in the environment during the use phase.

It was not possible to reach a conclusion in the case of microplastics used in medical devices as not enough information on the technical function provided by microplastics in this particular application was available in the restriction dossier. Furthermore, for two additional uses of microplastics it was not possible to conclude on the necessity of the use for health and safety, and on its criticality for the functioning of society because the information on the end uses provided in the background document was too broad to properly determine the purposes of microplastics.

Overall, the assessment suggested that enough information is available in the background document of the restriction dossier for the authorities to determine on the essentiality of the uses of a substance of concern. Therefore, it is unlikely that drastic changes in the Restriction process under REACH are needed to implement the essential-use concept to guide decision-making on potential derogations from restrictions. However, this analysis suggests that an implementation of the essential-use concept would imply a need for the authorities to have a very detailed understanding of the supply chain of the chemicals of concern, which could be extremely challenging in certain cases.

Table 4-1 Change of outcome of the decision-making on derogations in the restriction on intentionally added microplastics if the essential use would have been applied

Derogation as proposed by the dossier submitter	Main reason for derogation	Conclusion on derogation following the essential-use concept
Natural polymers not chemically modified	Negligible risk/exposure	Derogation proposed
Polymers which are (bio)degradable	Negligible risk/exposure	Derogation proposed
Polymers with solubility > 2g/L	Negligible risk/exposure	Derogation proposed
Substances, mixtures or articles where microplastic is contained by technical means to prevent releases	Negligible risk/exposure	Not evaluated
Substances, mixtures or articles where the physical properties of the microplastic are permanently modified	Negligible risk/exposure	Not evaluated
Substances, mixtures or articles where the microplastics are permanently incorporated in a solid matrix	Negligible risk/exposure	Not evaluated
Substances or mixtures regulated under Regulation (EC) No. 2019/1009 on Fertilising Products	Already regulated elsewhere	Derogation proposed
Medicinal products for human or veterinary use	Already regulated elsewhere	Derogation proposed
Substances or mixtures containing food additives	Already regulated elsewhere	Derogation proposed
Sludge and compost	Microplastic present as impurities	Derogation proposed
Food and feed	Microplastic present as impurities	Derogation proposed
Substances or mixtures containing microplastics used at industrial sites	Out of scope of the intended restriction	Derogation proposed
IVD	Costs outweigh the risk	Derogation proposed
Medical devices (where microplastics cannot be contained during end use)	Lack of alternatives	Difficult to assess
Rinse-off cosmetic products	Time needed for transition	No derogation
Detergents and maintenance products without microbeads	Lack of alternatives	Derogation proposed
Fragrance encapsulates	Lack of alternatives	No derogation
Agricultural & horticultural uses: Controlled release fertilisers & fertiliser additives	Lack of alternatives	Derogation proposed
Agricultural & horticultural uses: Capsule suspensions PPPs & coated seeds	Lack of alternatives	Derogation proposed
Leave-on cosmetic products	Lack of alternatives	No derogation

REACH Authorisation

The detailed analysis of the guidance documents for companies to prepare an AfA is provided in **Annex B**. Overall, the analysis suggests that applicants are expected to provide enough information in their AfA for the authorities to conclude on the essentiality of the use applied for, especially as part of the socio-economic analysis. However, as "*the level of detail and scope of the socio-economic analysis […] shall be the responsibility of the applicant for authorisation*", it was necessary to analyse actual AfA to determine whether applicants do provide enough information to the authorities for applying the essential-use.

The analysis of a pool of 100 AfA which followed the "SEA route" suggested that overall enough information was provided in the applications to conclude on the essentiality of the use applied for. However, for one third of the AfA analysed, the information related to the technical function of the substance of concern and its end uses was too broad to be able to conclude on the essentiality of the use applied for. It was recommended that the the use descriptors system under REACH was revised to ensure an easier application of the essential-use concept. The whole analysis of the AfAs following the essential-use concept is provided in **Annex C**.

5 Perspectives

Overall, this study suggests that no major changes in the current chemical regulations are necessary to implement the essential-use concept as a tool to guide decision-making on potential derogations to restrictions on uses of the most harmful chemicals. It brings a potential to change the perspective for decision-makers to evaluate derogations to restrictions which may help to narrow down the range of potential derogations/exemptions to be discussed. However, it is critical to properly define specific criteria for a use to be considered as essential to make sure that the concept is enforceable. Furthermore, implementing the essential-use concept would imply that the authorities get a very good understanding of the uses of the chemicals of concern, their supply chains, and the availability of potential alternatives, which could be challenging for chemical substances with complex supply chains and with broad range of end uses. Efforts on the correct communication of such technical details are also critical to make sure that the essential-use concept is comprehensible. Whether the implementation of the essential-use concept in chemical regulations would have a major impact on the efficiency of the regulatory processes should be the focus of further work.

6 References

(1) United Nations. *The Montreal Protocol on Substances that Deplete the Ozone Layer*. Ozone Secretariat website. https://ozone.unep.org/treaties/montreal-protocol (accessed 2023-11-16).

(2) United Nations. *Decision IV/25 in the Montreal Protocol: Essential uses*. https://ozone.unep.org/treaties/montreal-protocol/meetings/fourth-meeting-parties/decisions/decision-iv25-essential-uses?q=fr/meetings/fourth-meeting-parties-montreal-protocol/decisions/decision-iv25-utilisations-essentielles (accessed 2023-11-16).

(3) T. Cousins, I.; Goldenman, G.; Herzke, D.; Lohmann, R.; Miller, M.; A. Ng, C.; Patton, S.; Scheringer, M.; Trier, X.; Vierke, L.; Wang, Z.; C. DeWitt, J. The Concept of Essential Use for Determining When Uses of PFASs Can Be Phased Out. *Environ. Sci. Process. Impacts* **2019**, *21* (11), 1803–1815. https://doi.org/10.1039/C9EM00163H.

(4) European Commission. *Chemicals strategy for sustainability*. European Commission website. https://environment.ec.europa.eu/strategy/chemicals-strategy_en (accessed 2023-11-16).

(5) ZeroPM. Making the Essential-Use Concept Enforceable, Effective and Understandable - a Communication from the Horizon 2020 Project ZeroPM. https://zeropm.eu/wp-content/uploads/2022/11/ZeroPM_essential_use_final-1.pdf (accessed 2024-03-21).

(6) Directorate-General for Environment (European Commission); WSP Environment & Infrastructure Solutions; Bougas, K.; Flexman, K.; Keyte, I.; Corden, C. *Supporting the Commission in Developing an Essential Use Concept*; Publications Office of the European Union: LU, 2023.

(7) United Nations Environment Programme. *Overview of the Stockholm Convention*. Stockholm Convention website. https://www.pops.int/TheConvention/Overview/tabid/3351/Default.aspx (accessed 2023-11-16).

(8) European Chemicals Agency. *The Restriction process under REACH*. ECHA website. https://echa.europa.eu/restriction-process-phase-1 (accessed 2023-11-16).

(9) European Chemicals Agency. *Authorisation process - Application for Authorisation*. ECHA website. https://echa.europa.eu/phase-3-application-for-authorisation (accessed 2024-02-21).

(10) United Nations Environment Programme. *The POPs*. https://chm.pops.int/TheConvention/ThePOPs/tabid/673/Default.aspx (accessed 2024-03-21).

(11) United Nations Environment Programme. *The New POPs under the Stockholm Convention*. Stockholm Convention website. https://chm.pops.int/?tabid=2511 (accessed 2023-11-16).

(12) European Chemicals Agency. *Understanding REACH*. ECHA website. https://echa.europa.eu/regulations/reach/understanding-reach (accessed 2023-11-16).

(13) European Chemicals Agency. *Substances restricted under REACH*. ECHA website. https://echa.europa.eu/substances-restricted-under-reach (accessed 2023-11-16).

(14) European Chemicals Agency. *Authorisation process - Substance of very high concern identification*. ECHA website. https://echa.europa.eu/substances-of-very-high-concern-identification-explained (accessed 2024-02-21).

(15) European Chemicals Agency. *Authorisation process - Recommendation for the Authorisation List*. ECHA website. https://echa.europa.eu/regulations/reach/authorisation/recommendation-for-inclusion-in-the-authorisation-list (accessed 2024-02-21).

(16) European Chemicals Agency. *Authorisation List*. ECHA website. https://echa.europa.eu/authorisation-list (accessed 2023-11-16).

(17) Dalglish, S. L.; Khalid, H.; McMahon, S. A. Document Analysis in Health Policy Research: The READ Approach. *Health Policy Plan.* **2020**, *35* (10), 1424–1431. https://doi.org/10.1093/heapol/czaa064.

(18) European Chemicals Agency. *Adopted opinions and previous consultations on applications for authorisation*. ECHA website. https://echa.europa.eu/applications-for-authorisation-previous-consultations (accessed 2023-11-16).

(19) European Chemicals Agency. Final Background Document of the Restriction Dossier on Intentionally Added Microplastics. **2020**.

(20) European Chemicals Agency. *Guidance on the Preparation of an Application for Authorisation: January 2021*; Publications Office of the European Union: LU, 2021.

7 Annexes

Annex A: Implications for Implementing the "Essential-Use" Concept in Chemical Regulations

Note: This annex is currently in preparation for submission in a peer-reviewed journal. Supplementary files referred to in Annex A can be found at the ZeroPM Zenodo Page.

Implications for Implementing the "Essential-Use" Concept in Chemical Regulations

Romain Figuière[1*], Zhanyun Wang[2], Ian T. Cousins[1]

[1] Department of Environmental Science, Stockholm University, Stockholm, Sweden

[2] Empa – Swiss Federal Laboratories for Materials Science and Technology and Society Laboratory, St. Gallen, Switzerland

*: Corresponding author: romain.figuiere@aces.su.se

Abstract

The Stockholm Convention and the EU REACH Regulation are two broad regulatory frameworks which have been established for the sound management of hazardous chemicals at the global and European level, respectively. While those processes are working well, discussions have taken place in order to make them more efficient. Among other, the European Commission is considering implementing the "essential-use" concept in the restriction and authorisation processes of the REACH Regulation in order to guide decision-making for phasing-out the uses of the most harmful chemicals. The aim of this study is to shed light on how the "essential-use" may be used to improve existing regulatory systems by evaluating how existing regulatory outcomes match the essential-use concept as defined in the Montreal Protocol, and by identifying reasons for discrepancies. As a case study, the "essential-use" concept was applied using the same information presented in a restriction dossier under the REACH Regulation to evaluate how an implementation of the concept could have influenced the decisions-making. Overall, this study suggest that it is not needed to drastically change the chemical regulations to implement the essential-use concept in the decision-making. However, for the authorities to properly understand the purpose of a substance of concern, it would implicates that the industry would need to provide more technical information on the actual functions provided by a substance of concern if they wish to get a derogation for their use, similar to what is being done under the REACH Authorisation process. Further work should investigate whether the information provided by companies in applications for authorisation is enough to determine whether a use is necessary for health and safety, or is critical for the functioning of society.

1. Introduction

Chemical pollution, together with climate change and biodiversity loss, has been identified as a triple planetary crisis to humanity and the environment[1], especially by those substances that may remain intact in the environment for a long period of time and become widely distributed geographically.[2–4] Driven by public and scientific concern, many regulatory frameworks have been established for the sound management of chemicals at the different levels. Among them, two important ones are the global

Stockholm Convention on Persistent Organic Pollutants (POPs) and the European Union (EU)'s REACH Regulation – Registration, Evaluation, Restriction and Authorisation of Chemicals.

Adopted in 2001, the Stockholm Convention is a global treaty to protect human health and the environment from POPs[5]. Apart from the initial "dirty-dozen" POPs, the Convention includes a process to list new chemicals. It starts with nomination by a Party, triggering a three-step scientific assessment by the POPs Review Committee (POPRC): 1) screening the chemical(s) against the POP criteria in Annex D, 2) assessing their risk profile in accordance with Annex E, and 3) developing a risk management evaluation that assess social-economic aspects in accordance with Annex F and making recommendations to the Conference of the Parties (COP), the Convention's governing body. In its recommendations, POPRC can include specific use(s) and related production of the chemical(s) to be exempted from the Convention's measures. Then, COP makes decisions on the listing based on the POPRC recommendations and any additional information presented by Parties and observers during its meeting. Once listed and ratified, Parties to the Convention are obliged to eliminate or restrict the chemical(s), except for the exemptions. As of November 2023, 34 chemicals or groups of chemicals are listed under the Convention, and 4 more are under evaluation or ready for decisions by COP.

EU REACH entered into force in 2007. It includes three key components: registration of chemicals on the EU market; evaluation of them for their safety; and when risks associated with specific substance(s) are not adequately controlled, their uses may be restricted through the authorisation or the restriction processes[6]. When a substance is identified as a Substances of Very High Concern (SVHC) and subsequently included in the Annex XIV, it will be subject to the authorisation process[7]. As of November 2023, 476 substances have been identified as SVHCs[8], and 59 entries covering 141 of those substances have made to the Annex XIV of REACH for authorisation[9]. In the latter cases, the European Commission sets a sunset date for all uses of the substance to cease. After the sunset date, if a company wishes to continue using the substance, it must apply for authorisation, demonstrating either that the risks from its use of the SVHC is adequately controlled, or that the socio-economic benefits linked to the use of the SVHC outweighs its risk, and that no suitable alternatives substances or technologies are available to the applicant before the sunset date[10].

Alternatively, a restriction may be applied, usually limiting or banning the manufacture, placing on the market, or the uses of specific substance(s)[11]. For the substance(s), a restriction dossier is first prepared, including information on hazards and risks, on availability of alternatives, and a justification for a restriction at the EU level. It can also identify so-called "derogations" of certain uses to be potentially exempted from the restriction. The restriction dossier will then be publicly consulted. Building on the dossier and associated public consultations, the Risk Assessment and Socio-economic Assessment Committees of the European Chemicals Agency (RAC and SEAC) then develop opinions for the European Commission. In particular, based on a socio-economic analysis and an analysis of potential alternatives, SEAC provides its view on uses to be potentially exempted. The Commission then takes the final decision on the restriction and exemptions under REACH. As of November 2023, a total of 78 entries of restrictions have been added to the Annex XVII of REACH, covering 2127 substances[12,13].

While these processes under the Stockholm Convention and EU REACH are working well, discussion has taken place on potential optimization. For example, the Stockholm Convention does not specify criteria for determining exemptions, but only request specific information as outlined in Annex F for consideration, including: efficacy and efficiency of possible control measures, alternatives, positive and/or negative societal impacts of possible control measures, waste and disposal implications, and status of control and monitoring capacity[14,15]. It is noted that for recent several listings, COP agreed to more exemptions than what was recommended by POPRC. In some instances, exemptions go beyond those evaluated by POPRC, while in others, uses rejected by POPRC are granted exemptions by COP. It is recently suggested to delve into the reasons behind these decisions to identify good ways for future practices[15]. Further, the European Commission recently concluded in the second REACH review that the authorisation process is too heavy and inflexible and that the restriction process is too slow to sufficiently protect consumers and professional users[16,17]. Therefore, the Commission wishes to revise both processes, particularly to make them more efficient and effective to achieve a higher level of protection of human health and the environment[18,19]. To that end, the Commission considers implementing the “essential-use” concept as a tool to optimize both processes under REACH[19].

The essential-use concept was first introduced in the Montreal Protocol for phasing out ozone-depleting substances except for certain essential uses. In the Decision IV/25 adopted in 1992, the Parties agreed that a “controlled substance should qualify as ‘essential’ only if: (1) it is necessary for the health, safety or is critical for the functioning of society (encompassing cultural and intellectual aspects); and (2) there are no available technically and economically feasible alternatives or substitutes that are acceptable from the standpoint of environment and health” [20,21]. In 2019, Cousins et al. suggested further using the essential-use concept to guide phase-out of per- and polyfluoroalkyl substances (PFASs) [22,23]. Currently, work is ongoing at the EU level to seek for clarities on whether and how to operationalize the essential-use concept in the EU chemical regulations[24].

This study aims to shed light on how the essential-use concept may be used to improve existing regulatory systems such as the EU REACH and the Stockholm Convention. It starts with evaluating how existing regulatory outcomes under the EU REACH and the Stockholm Convention match the concept, as defined in the Montreal Protocol, and identifying reasons for discrepancies. This analysis shows what has generally been established in the current regulatory systems with relevance to the essential-use concept. Then, a case study is conducted, applying the essential-use concept to the same information presented in the existing restriction under the EU REACH to assess how an implementation of the concept may influence restriction outcomes. The results of our analysis provide key insights on how a future implementation of the essential-use concept in the EU REACH, the Stockholm Convention and legislation in other jurisdictions may be built upon existing regulatory systems, and highlights important questions/factors to be considered in the implementation of the concept.

2. Methods

2.1 Evaluation of existing regulatory outcomes

The READ approach, a four-step method specifically developed for systematic analysis of policy documents[25], was followed to determine how existing regulatory outcomes under the EU REACH and the Stockholm Convention match the essential-use concept and to identify reasons for discrepancies.

Step 1—Readying the materials. In this first step, relevant policy documents were selected for analysis, covering both recommendations made by the relevant scientific subsidiary bodies and final regulatory decisions taken by the policy-making bodies.

For the EU REACH restrictions, the final SEAC opinions on the previous restriction proposals[12], and the associated final legal decision adopted by the European Commission.[12] Similarly, under the Stockholm Convention, the final risk management evaluations prepared by POPRC, and the corresponding final decision adopted by COP[26].

For the EU REACH authorisation, in addition to the SEAC opinions and related European Commission decisions of the previous authorisation cases, a list of the short-listed alternatives evaluated by companies in their applications for authorisation, published by ECHA, was taken into account. This list summarised the reasons for rejections of the alternatives according to the applicants, and whether they have identified a "most promising alternatives" for the use applied for as of June 2023[27].

Step 2—Extracting the data. Information on the derogations/exemptions that were recommended or rejected by SEAC or POPRC and for which reasons were manually collected, as well as the lists of derogations/exemptions in the final legal decisions. Furthermore, as explained above, an authorisation may be granted if the applicant successfully demonstrated that (1) the risks from its use of the SVHC is adequately controlled (so-called "adequate controlled route"), or that the socio-economic benefits linked to the use of the SVHC outweighs its risk (so-called "SEA route"); and (2) that no suitable alternatives substances or technologies are available to the applicant before the sunset date. Therefore, by definition all granted authorisations for specific uses satisfy one of the essential-use components, i.e. "there are no available technically and economically feasible alternatives or substitutes that are acceptable from the standpoint of environment and health". Thus, for the analysis of the authorisations under the EU REACH, information was collected for determining the argumentation route followed by the applicant, i.e., whether the "SEA route" or the "adequate controlled route".

Step 3—Analysing the data. The extracted data were manually analysed to capture the rationale for recommending or rejecting a derogation/exemption/authorisation by SEAC or POPRC. Then, the rationales were analyzed in terms of how they could be related to an element of the essential-use concept by grouping them into the following four categories: (1) a specific use is critical for health, safety or the functioning of society; (2) no alternatives are available for a specific use; (3) actors of a specific use need more time to transition towards an alternative; and (4) other reasons (e.g., negligible releases/exposure/risks, the chemical(s) present as impurities in other products, costs outweigh the benefits). The latter two do not belong to the essential-use concept, but were nevertheless helpful for understanding the regulatory rationales of derogations/exemptions/authorisations. Regarding the EU REACH Authorisation process, the collected data were analysed to determine (1) the number of alternatives identified per applications; (2) the number of applications where the applicants have identified a "most promising alternatives"; and (3) the reasons for rejections of the alternatives (i.e. not technically feasible, not economically feasible, alternative not available to the applicant, or no risk reduction compare to the substance of concern).

All the key information was stored in the Microsoft Excel Spreadsheets provided as the *Supporting Information* (Tables S1.1, S1.2 and S1.3), and it was analysed by using the pivot table function of Microsoft Excel.

Step 4—Distilling the findings. The analysis was further interpreted using basic tools (e.g. pivot tables) in Microsoft Excel to evaluate how the current regulatory outcomes match or differ from the essential-use concept.

2.2 Case study

The restriction on intentional use of microplastics under EU REACH served as a case study for further in-depth analysis. The essential-use concept was applied, using the approach recently released by the European Commission[24], to the same information used in the relevant public documents that was available to SEAC and POPRC, using the following three main steps:

Step 1—Scoping the use and function of the target chemicals. The functional-substitution concept[28] was followed to determine whether a chemical of concern is "fit-for-purpose", i.e., whether the substance is necessary for the technical function of the end-use. To do so, the information available in the restriction dossier was analysed to determine the uses and applications of the target chemicals, the chemical function (i.e., technical function) they provide, their end-use function, and their function as a service, as defined in a previous study[29]. In this study, the term "use" refers to a general description of the sector and/products the microplastics are used in while "application" refers to more specific example of product type, if relevant. Following the functional substitution approach, the "technical function" of a substance is determined by its physico-chemical properties; the "end-use function" refers to the function provided by the substance in the context of a specific product/industrial process; and the "function as a service" describes the service, i.e. the interest of having a specific product/industrial process with the specific function provided by the substance of interest[29,30].

Step 2—Assessing the necessity of the function of the target chemicals for health and safety and for the functioning of society. A list of possible criteria recommended in WSP (2023), listed in the *Supporting Information* (Tables S2.1 and S2.2), was used for the assessment[24].

Step 3—Assessing the availability of safer alternatives. It was assumed that alternatives were available for those uses that SEAC recommend a derogation due to reasons other than a lack of alternatives. Additionally, the information available in the restriction dossier was analysed to determine whether the safety of potential alternatives had been evaluated.

3. Results and Discussion

3.1 Overview of the regulatory outcomes as of November 2023 analysed

For restrictions under the EU REACH, SEAC issued final opinions on 45 restriction dossiers. For 14 restriction dossiers, no derogation was proposed by the dossier submitter. For 2 restriction dossiers, derogations were proposed by the dossier submitter, but SEAC did not recommend them in its final opinions. In total, SEAC recommended derogations for 184 different uses to the European Commission in 29 different dossiers. Restrictions on lead in projectiles and in fish sinkers and lures for outdoor activities, perfluorooctanoic acid (PFOA), and intentionally added microplastics are the dossiers with the highest number of proposed derogations assessed by SEAC (i.e., 24, 22, and 20, respectively). The European Commission published a decision on 28 restriction dossiers, and granted derogations for 102 different use cases.

For authorisations under the EU REACH, 544 applications for authorisation have been submitted to ECHA for uses of 34 SVHCs. SEAC issued opinions on 448 of those applications, and the European Commission published a decision for 328 of them.

Under the Stockholm Convention, 22 substances had been listed by the time of the analysis. For 9 listed substances, no exemption was recommended by POPRC to COP. In total, POPRC recommended exemptions for a total of 48 different use cases of 12 substances. Perfluorooctanesulfonic acid (PFOS), PFOA and short-chain chlorinated paraffins were the substances for which the highest number of exemptions discussed (i.e., 13, 11, and 9, respectively).

3.2 Reasoning for granting derogations/authorisations/exemptions in the existing outcomes

Figure 1 presents the main reasons for granting derogations, authorisations and exemptions for the existing regulatory outcomes under the EU REACH and the Stockholm Convention analysed in this study. All extracted data are listed in the *Supporting Information*, along with the exact quotes from the

SEAC final opinion and from the POPRC risk management evaluation referring the reasoning for recommending (or not) (Table S1 and S2) and related to the applications for authorisation (Table S3).

Under the Stockholm Convention

In 15 cases, POPRC recommended to grant exemptions because more time is needed to transition to an alternative. In 23 cases, exemptions were recommended because no alternatives were identified at the time of the listing of the substance for elimination. No exemptions were recommended solely because the use was necessary for health and safety, or critical for the functioning of society, while the criticality of the use for society was mentioned as part of the arguments for recommending an exemption in 13% of the cases. In 3 cases, POPRC recommended to grant an exemption due to the difficulty to implement the restriction, i.e., for the uses of decaBDE, octaBDE and pentaBDE in recycling products. One exemption for use of PFOS in chemically driven oil production was recommended by POPRC for other reasons than the ones previously mentioned.

While in 48 cases, COP followed the POPRC recommendations in regards of granting exemptions or not, some discrepancies have been observed. For the uses of PFOA in membranes intended for medical textiles and filtration in water treatments, and in photo-imaging applications, COP granted time-limited exemptions, although POPRC recommended otherwise as the phase-out of PFOA in these uses have been observed. Furthermore, COP granted an exemption for the use of PFOA in industrial waste heat exchanger, equipment industrial sealants, high-voltage electrical wire and cables for power transmission, and fluoroelastomers for the production of O-rings, v-belts and plastic accessories for car interiors, although this particular use was not discussed in the risk management evaluation by POPRC. Similarly, COP granted exemptions for the use of decaBDE in parts of vehicles, and for the use of chlorinated naphthalene as intermediates in the production polyfluorinated naphthalene, although these uses were not discussed in the evaluation by POPRC. For 10 uses of PFOS, COP granted exemptions for a significantly lower number of applications compared to the recommendations of the POPRC probably due to the progress made by countries to phase-out uses of PFOS.

Under the EU REACH

For the 29 restriction dossiers with SEAC opinions on derogations, 36 derogations out of the 184 cases have been recommended by SEAC because the industry needed more time to transition to an alternative. In 28 cases, derogations were recommended because the chemical users did not identify a suitable alternative at the time of the restriction. In contrast to the Stockholm Convention cases, 4 derogations were recommended because the related use was necessary for health and safety, or critical for functioning of society: the use of skin sensitising, irritative and/or corrosive substances in personal protective equipment and medical devices; the use of formaldehyde in articles for industrial and professional uses; the use of perfluorohexanoic acid (PFHxA) in personal protective equipment; and the use of "Dechlorane Plus" in medical imaging applications and radiotherapy devices. Meanwhile, despite not being the primary reason for granting a derogation, the criticality of the use for society has been mentioned by SEAC as an argument for granting a derogation in 14% of the cases. 63% (i.e., 116 cases) of the derogations were recommended by SEAC for reasons other than the ones previously mentioned. These include 6 main sub-categories of reasons: the particular use is already regulated elsewhere (18 cases); the enforcement of the restriction on the use would be too difficult (17 cases); the particular use is outside of the scope of the restriction (20 cases); the substance of concern is present as impurities in the particular use (14 cases); the estimated releases, exposure and/or risk related to the use are expected to be negligible (22 cases); and the costs of the phase out of the substance of concern for the particular use outweigh the risk (10 cases). For the remaining 15 cases of derogations, the reasoning was really specific to the individual use cases and could not be generalized.

The European Commission followed the SEAC recommendations in 112 cases, whereas in 6 cases, discrepancies were observed in the following three types: 2 cases with a shorter transitional period than in the SEAC opinion (the use of DecaBDE in the production, maintenance, repair or modifications of aircraft articles, and the use of lead as stabiliser in specific PVC articles containing recycled PVC in building and construction applications); 1 case with derogations for which SEAC evaluated that no derogations were needed (the use of phthalates in aerospace and automotive articles); and 3 cases with a longer transitional period (the use of N,N-dimethylformamide as solvent in polyurethane coating processes of textile and paper material and in the dry and wet spinning processes of synthetic fibres, and the use of chrysotile by one specific company).

Regarding the authorisation process, a previous study demonstrated that the essential-use concept could guide decision-making on applications for authorisation only in the cases where the applicants followed the “SEA route”[31]. Therefore, any granted authorisation for applications which followed the “adequate controlled route” were considered as derogations granted for other reasons than the “essential-use” components, and for which it is highly unlikely that the “essential-use” concept would have changed the outcome of the decision. As illustrated in Figure 1-B, only 19 applications fall under the “adequate controlled route”, for the uses of phthalates and bis(2-methoxyethyl) ether.

Further, when applicants stated that they have identified a “most promising alternative” in their application for authorisation, it was considered that SEAC recommended to grant an authorisation because more time is needed for the transition. If it was not the case, then it was considered that SEAC recommended to grant an authorisation because alternatives were lacking for the use applied for. As illustrated in figure 1-B, in 78% of the cases (n = 348), SEAC recommended to grant authorisation because the applicants were lacking alternatives at the time of the application.

In the majority of the cases (84.45%, n = 277), the European Commission followed the SEAC’s recommendations, while in some other cases, discrepancies were noted as the following. In 14 cases (12 uses of lead chromates, 1 use of trichloroethylene, and 1 use of sodium dichromate), the European

Commission granted an authorisation with a shorter review period than the one SEAC recommended on the basis that it was difficult to assume the non-suitability of the alternatives for a long period and they assumed less time needed by the companies to implement alternatives. For 2 uses of bis(2-ethylhexyl) phthalate, the European Commission granted a shorter review period due to some deficiencies in the exposure assessment in the workplace made by the applicants. For 2 uses of "4-(1,1,3,3-tetramethylbutyl)phenol ethoxylated", the European Commission granted a review period longer than the one SEAC recommended because they disagreed with SEAC's justifications in setting the length of the review period. For 20 uses of chromates, the European Commission granted only a "partial authorisation" as they argued that the SVHCs should not be used for parts of the use applied for where "the key functionality [of the SVHC] is not necessary for the use". Similarly, the European commission granted only partial authorisation for 3 additional uses of chromates because the scope of the use applied for was too broad. SEAC did not recommend to grant authorisation for 2 uses of "pitch, coal tar, high temperature" because the applicants failed to demonstrate that the socio-economic benefits of their use outweigh the risk and that no alternatives are suitable for their use, and for 2 uses of chromates because the applicants failed to demonstrate that no suitable alternatives were available for their use. The European Commission agreed with this conclusion.

3.3 How does the essential-use concept differ from current chemical regulations?

Under the Stockholm Convention, the majority of exemptions were granted for reasons which relate to the components of the essential-use concept. Only in 9.1% of the cases, exemptions were granted for other reasons, but mainly due to difficulties in enforcing the restriction. Thus, an official integration of the essential-use concept would have not significantly altered existing outcomes under the Convention. This might also apply to future cases, should the Convention continue the way it works as it is now.

Regarding the EU REACH Authorisation process, reasoning to grant the authorisations differed from the essential-use concept only in 4.2% of the cases. As demonstrated in a previous study, it would not be legal for the European Commission to refuse to grant an authorisation if the applicant demonstrated that the risk resulting from their use is adequately controlled (i.e., the "adequate controlled route"), even when the use would be deemed non-essential[31]. Therefore, the essential-use concept would not have influenced the outcome of these decisions. Whether it would have influenced the decision-making on the authorisations which followed the "SEA route" is difficult to assess as it would require an in-depth analysis of the information in the existing applications for authorisation. Such an in-depth analysis goes beyond the purpose of this study and may warrant future work.

The reasoning for granting derogations under the current EU REACH Restriction process presents the most discrepancies with the essential-use concept. As mentioned above, 63% of the derogations were recommended by SEAC for reasons other than the components of the essential-use concept. Among them, many derogations have been agreed upon the basis of technical reasons specific to enforcement of the restriction process under REACH, and implementing the “essential-use” concept would unlikely change these derogations. That being said, implementing the “essential-use” concept could have influenced the decision-making only on derogations which were granted for uses for which (1) it was believed the resulting risk was negligible or (2) the costs of applying the restriction would outweigh the risk of the continued use, totalling 17.4% of the cases.

To summarise, our analysis suggest that implementing the essential-use concept will not result in a drastic change in chemical regulations in terms of granting derogations/exemptions/authorisations. In other words, due to existing incorporation of some elements of the essential-use concept, existing chemical regulations such as the EU REACH and the Stockholm Convention can readily integrate the concept, which can help to further narrow down some non-essential derogations/exemptions/authorisations. In the following, the restriction dossier on intentionally added microplastics under the EU REACH served as a case study to evaluate whether the information available to the decision-makers at the time was enough for them to determine if a use is essential or not when deciding on potential derogations.

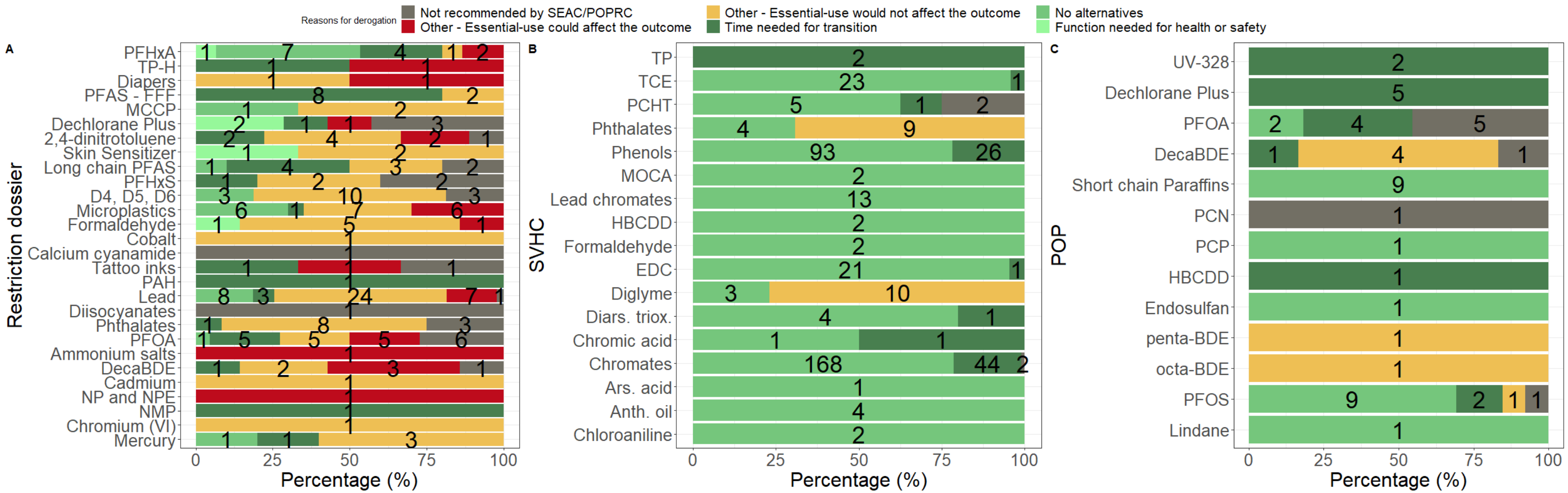

Figure 1 Reasons for derogations in former REACH restriction dossiers (A), applications for authorisation under REACH (B), and substances listed under the Stockholm Convention (C)

Note: To facilitate the reading of the figures, numbers of several restriction dossiers, and numbers for applications for authorisation for the continued uses of several SVHC were aggregated as follow:

(A) "Lead" represents an aggregation of the data related to 5 different restriction dossiers (i.e., lead in projectiles (for firearms and air guns), and in fishing sinkers and lures for outdoor activities; lead and its compounds in shots for shooting in wetlands; lead and its compounds as PVC stabilizer; lead and its compounds in consumer articles; and lead and its compounds in jewelry);

(B) "Phthalates" represents an aggregation of the data related to bis(2-ethylhexyl) phthalate and dibutyl phthalate; "Phenols" represents an aggregation of the data related to 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated, and 4-nonylphenol, branched and linear, ethoxylated; "Lead chromates" represents an aggregation of the data related to lead chromate, lead chromate molybdate sulphate red (C.I. pigment red 104), and lead sulfochromate yellow (C.I. pigment yellow 34); "Chromates" represents an aggregation of the data related to ammonium dichromate, chromium trioxide, dichromium tris(chromate), pentazinc chromate octahydroxide, potassium chromate, potassium dichromate, potassium hydroxyoctaoxodizincatedichromate, sodium chromate, sodium dichromate, and strontium chromate.

Abbreviations:

(A) NMP: 1-methyl-2-pyrrolidone; NP and NPE: 4-nonylphenol, branched and linear, and 4-nonylphenol, branched and linear, ethoxylated; DecaBDE: Bis(pentabromophenyl) ether; Ammonium salts: inorganic ammonium salts; PFOA: perfluorooctanoic acid, its salts and PFOA-related substances; Phthalates: diisobutyl phthalate, dibutyl phthalate, benzyl butyl phthalate, and bis(2-ethylhexyl) phthalate; PAH: Polycyclic-aromatic hydrocarbons; Tattoo inks: substances in tattoo inks and permanent make-up; Cobalt: cobalt carbonate, cobalt di(acetate), cobalt dichloride, cobalt dinitrate, and cobalt sulphate; Formaldehyde;: formaldehyde and formaldehyde releasers; Microplastics: intentionally added microplastics; D4, D5, D6: octamethylcyclotetrasiloxane, decamethylcyclopentasiloxane, and dodecamethylcyclohexasiloxane; PFHxS: perfluorohexane-1-sulphonic acid, its salts and related substances; Long chain PFAS: perfluorononan-1-oic acid (PFNA), nonadecafluorodecanoic acid (PFDA), henicosafluoroundecanoic acid (PFUnDA), tricosafluorododecanoic acid (PFDoDA), pentacosafluorotridecanoic acid (PFTrDA), heptacosafluorotetradecanoic acid (PFTDA), including their salts and precursors; Skin Sensitizer: Skin sensitizing , irritative and/or corrosive substances; Dechlorane Plus: 1,6,7,8,9,14,15,16,17,17,18,18-Dodecachloropentacyclo[12.2.1.16,9.02,13.05,10]octadeca-7,15-diene; MCCP: medium-chain chlorinated paraffins; PFAS – FFF: per- and polyfluoroalkyl substances in firefighting foams; Diapers: Substances in single-use baby diapers; TP-H: terphenyl, hydrogenated; PFHxA: undecafluorohexanoic acid, its salts and related substances;

(B) Chloroaniline: 4,4’-methylenebis[2-chloroaniline]; Anth. Oil: Anthracen oil; Ars. acid: Arsenic acid; Diars. triox.: diarsenic trioxide; Diglyme: bis(2-methoxyethyl) ether; EDC: 1,2-dichloroethane; formaldehyde: formaldehyde, oligomeric reaction products with aniline; HBCDD: hexabromocyclododecane, alpha-hexabromocyclododecane; beta-hexabromocyclododecane, gamma-hexabromocyclododecane; MOCA: 2,2’-dichloro-4,4’-methyelenedianiline; PCHT: pitch, coal tar, high temperature; TCE: trichloroethylene; TP: trixylyl phosphate;

(C) PFOS: perfluorooctane sulfonic acid~~ate~~; octa-BDE: commercial octabromodiphenyl ether (its components: hexabromodipenyl & heptabromodihenyl); penta-BDE: commercial pentabromodiphenyl ether (ist components tetra- & hexabromodiphenyl ether); HBCDD: hexabromocyclododecane; PCP: pentachlorophenol and its salts and esthers; PCN: chlorinated naphthalenes;

3.4 Lessons learnt from the case study

Background information on the restriction dossier on intentionally added microplastics is presented in the *Supporting Information* (S3 and S4). The whole assessment of the essentiality of the identified uses of microplastics is presented in a separate Microsoft Excel Spreadsheet (Table S5.0), including our conclusions on potential derogations following the essential-use concept. The following presents the key lessons learnt from the case study.

Assessment of the essentiality of intentionally added microplastics

In total, 10 uses and 29 applications were evaluated by the dossier submitter. Out of the 29 applications, enough information was available in the restriction dossier to determine the technical function of microplastics, their end-use function and the service they provide for 22 cases.

Microplastics are not fit-for-purpose (i.e. whether the substance is necessary for the technical performance of the end-use) when being used in rinse-off cosmetic products and where they are not used as microbeads. Indeed, the dossier submitter stated that microplastics in these cases are mainly used as opacifiers to give the product a “milky texture” to improve the consumer perception, which is not necessary for the technical performance of the end-product. Such cases can be directly assigned as non-essential without further assessing whether the use meets individual components of the essential-use concept. In all other cases, the uses of microplastics could be considered as fit-for-purpose. It is important to note that in some cases, microplastics provides several functions to the products, which are not all fit-for-purpose. For example, microplastics used in detergents and maintenance products which are not considered as microbeads are present in the products for their functions as rheology modifiers, anti-foaming agents and/or complexing agents, but also as opacifiers. Although the former functions could be considered as fit-for-purpose as these functions improve the efficacy of the detergent product, the latter function only aims at improving consumer perception, which is not necessary to its technical performance.

For 15 of the 21 cases for which the use of microplastics is fit-for-purpose, it has been assessed by the authors that the function(s) provided by microplastics is necessary for health and safety and/or is critical for the functioning of society. It has been considered that the use of microplastic was not necessary for society when they are used as flagrance encapsulate in detergents and maintenance products, in cosmetic products, and in food additives, as none of these use cases meet any of the criteria listed in WSP (2023) and in the *Supporting Information* (S2). Based on the information contained in the restriction dossier, it is not possible to determine whether the function provided by microplastics is necessary for society when there are used in polish, and in paints and coatings as no information about the end-use of the products was provided. For example, a paint with friction resistance and anti-slips effects could be considered as critical for the functioning of society if it used for road marking, but not if it used for decorative purposes.

Out of the 15 cases for which the use of microplastics is fit-for-purpose, and necessary for health and safety and/or is critical for the functioning of society, no safer alternatives were available in 11 cases in agricultural and horticultural products, *in vitro* diagnostic devices, and detergents and maintenance products, only in the case where microplastics are not used as microbeads. It is important to note that the dossier submitter did not evaluate whether identified potential alternatives to microplastics were safer. At best, only a brief qualitative description of the hazard profile of the alternatives is provided in the restriction dossier. For the other 4 applications of microplastics in medical devices, not enough information on the function provided by microplastics is available in the restriction dossier to conclude on the essentiality.

The conclusions on the derogations which have been proposed by SEAC at the time of the restriction dossier and by the authors following the essential-use concept are shown in table 1. Based on the present analysis, it is likely that derogations for uses of microplastics in cosmetics (both rinse-off and leave-on cosmetic products), and as fragrance encapsulates would not have been proposed as these uses would not be considered as necessary for health and safety, or critical for the functioning to society according to WSP (2023)[24]. Furthermore, as explained previously, it is likely that derogations for uses for which it is believed that releases of microplastics would be negligible would not be proposed under the essential-use concept as the assessment would be focused on the use and function of the substance, and not on the exposure which would result from its use.

Table 1 Potential changes on the decision-making of derogations in the microplastics restriction dossier if the essential-use concept would have been applied

Derogation as proposed by the dossier submitter	Main reason for derogation	Conclusion by the authors on the derogation following the essential-use concept
Natural polymers not chemically modified	Negligible risk/exposure	Derogation proposed
Polymers which are (bio)degradable	Negligible risk/exposure	Derogation proposed
Polymers with solubility > 2g/L	Negligible risk/exposure	Derogation proposed
Substances, mixtures or articles where microplastic is contained by technical means to prevent releases	Negligible risk/exposure	Not evaluated
Substances, mixtures or articles where the physical properties of the microplastic are permanently modified	Negligible risk/exposure	Not evaluated
Substances, mixtures or articles where the microplastics are permanently incorporated in a solid matrix	Negligible risk/exposure	Not evaluated
Substances or mixtures regulated under Regulation (EC) No. 2019/1009 on Fertilising Products	Already regulated elsewhere	Derogation proposed
Medicinal products for human or veterinary use	Already regulated elsewhere	Derogation proposed
Substances or mixtures containing food additives	Already regulated elsewhere	Derogation proposed
Sludge and compost	Microplastic present as impurities	Derogation proposed
Food and feed	Microplastic present as impurities	Derogation proposed
Substances or mixtures containing microplastics used at industrial sites	Out of scope of the intended restriction	Derogation proposed
IVD	Costs outweigh the risk	Derogation proposed
Medical devices (where microplastics cannot be contained during end use)	Lack of alternatives	Difficult to assess
Rinse-off cosmetic products	Time needed for transition	No derogation
Detergents and maintenance products without microbeads	Lack of alternatives	Derogation proposed
Fragrance encapsulates	Lack of alternatives	No derogation
Agridultural & horticultural uses: Controlled release fertilisers & fertiliser additives	Lack of alternatives	Derogation proposed
Agridultural & horticultural uses: Capsule suspensions PPPs & coated seeds	Lack of alternatives	Derogation proposed
Leave-on cosmetic products	Lack of alternatives	No derogation

Lessons learnt from the case study: opportunities and challenges of the essential-use concept

Overall, the case study demonstrated that the evaluation of potential derogations following the essential-use concept would be more focused on the functions provided by the substance of concern and its actual benefits to society, rather than on the relevance of the risk the specific use represents. It was not possible to reach a conclusion on the essentiality of the use of microplastics for 4 applications out of the 29 which were evaluated based on the information provided in the restriction dossier. The result of the case study suggests that enough information provided in restrictions dossier to perform essentiality assessment, and that there is no need for drastic changes in the process for implementation of the concept in the decision-making.

For ten applications, microplastics provide more than one function to the end-use, i.e. provide more than one service. In those cases, it might be more difficult to find a suitable alternative as it is unlikely than one alternative can provide the same combination of functions. However, not all functions provided by microplastics could be considered as critical for technical performance of the end product. For instance, microplastics are used in detergents to improve the shelf life of the product and its efficiency, but also as opacifiers to provide a “milky” texture to the product in order to improve the consumer perception. Although it can be argued that an improvement of the product efficiency and shelf life are critical for its technical performance, the opacifiers function can be considered as “nice to have” but not critical (i.e. the product will perform just as well without opacifiers in the formulation). Therefore, when considering the suitability of alternatives, the evaluation should be focused on the most critical functions delivered by the substance of concern, and an alternative should not be disregarded if it does not provide the “nice to have” technical functions.

However, as previously mentioned it was not possible to evaluate whether microplastics are “fit-for-purpose” for seven applications as not enough information on their end-uses was provided in the restriction dossier which made difficult to understand the exact reasons why microplastics were used in the specific applications. Furthermore, for two applications (i.e. for microplastics used in food additives, and in paints and coatings), it was not possible to determine whether the functions provided by microplastics are necessary for the health and safety, or critical for society because the information provided on the end-uses of those applications was too broad. Therefore, an implementation of the essential-use concept in the decision-making would imply a need for the authorities to have a very good understanding of the supply chain of the chemicals, which can be extremely challenging in certain cases. If the dossier submitters do not have access to such information when preparing a restriction dossier, they could ask the industry to provide specific information during the public consultation on the technical function of the substance of concern, and how it relates to the end-use, if they want to seek for a derogation. Such an approach has already been taken for the restriction on uses of PFAS submitted in January 2023[32].

3.3 Can the essential-use concept improve the regulatory processes?

This study presented an application of the essential-use concept as a tool to guide the authorities in their decisions to grant a derogation for a specific use or not. The evaluation proposed would be based around an expert knowledge of the technical performance provided by the substance of concern in a specific use. This approach requires the authority to be very well aware of the whole supply chain of a chemical substance for them to properly understand the reasons why it is used. Such type of information is already required as part of an application for authorisation under the REACH Authorisation process. Therefore, the authorities could offer the possibility to the industry to request a time-limited derogation to a restriction where they should explain why they believe their use of a substance of concern is essential by providing similar information as in application for authorisation.

However, it is critical to properly define the scope of such request for derogation. Indeed, a scope which would be too wide could result into enforcement difficulties to distinguish between essential-use exemptions from end-uses which are not essential. This already happened in the REAHC Authorisation process in which the European Commission had to grant only partial authorisation for uses of chromates only for applications for which the functions provided by chromates is a “key functionality for the use”. On the other hand, a scope which would be too narrow could result into a high number of requests for derogations which would delay the decision-making. The European Commission already identified this as the main drawback of the REACH Authorisation process in the second REACH Review. How to determine the optimal scope of an essentiality assessment of a use should be the focus of further work.

4. Outlook

This study presented how the outcomes of chemical regulations differ from the essential-use concept components and evaluated whether the essential-use could be applied in the current state of those regulations. Further work should evaluate the potential of a clear and detailed essential-use framework to achieve the European Commission objectives to improve the regulatory processes efficiency. Further study could evaluate a change in the regulatory processes could have major impacts in the potential of the essential-use concept to improve the efficiency of the chemical regulations.

5. References

(1) United Nations Environment Programme. *Making Peace With Nature*. UNEP - UN Environment Programme. http://www.unep.org/resources/making-peace-nature (accessed 2024-03-27).

(2) Cousins, I. T.; Johansson, J. H.; Salter, M. E.; Sha, B.; Scheringer, M. Outside the Safe Operating Space of a New Planetary Boundary for Per- and Polyfluoroalkyl Substances (PFAS). *Environ. Sci. Technol.* **2022**, *56* (16), 11172–11179. https://doi.org/10.1021/acs.est.2c02765.

(3) Cousins, I. T.; DeWitt, J. C.; Glüge, J.; Goldenman, G.; Herzke, D.; Lohmann, R.; Ng, C. A.; Scheringer, M.; Wang, Z. The High Persistence of PFAS Is Sufficient for Their Management as a Chemical Class. *Environ. Sci. Process. Impacts* **2020**, *22* (12), 2307–2312. https://doi.org/10.1039/D0EM00355G.

(4) Persson, L.; Carney Almroth, B. M.; Collins, C. D.; Cornell, S.; de Wit, C. A.; Diamond, M. L.; Fantke, P.; Hassellöv, M.; MacLeod, M.; Ryberg, M. W.; Søgaard Jørgensen, P.; Villarrubia-Gómez, P.; Wang, Z.; Hauschild, M. Z. Outside the Safe Operating Space of the Planetary Boundary for Novel Entities. *Environ. Sci. Technol.* **2022**, *56* (3), 1510–1521. https://doi.org/10.1021/acs.est.1c04158.

(5) United Nations Environment Programme. *Overview of the Stockholm Convention*. Stockholm Convention website. https://www.pops.int/TheConvention/Overview/tabid/3351/Default.aspx (accessed 2023-11-16).

(6) European Chemicals Agency. *Understanding REACH*. ECHA website. https://echa.europa.eu/regulations/reach/understanding-reach (accessed 2023-11-16).

(7) European Chemicals Agency. *Guidance on the Preparation of an Application for Authorisation: January 2021*; Publications Office of the European Union: LU, 2021.

(8) European Chemicals Agency. *Candidate List of substances of very high concern for Authorisation*. ECHA website. https://echa.europa.eu/candidate-list-table?p_p_id=disslists_WAR_disslistsportlet&p_p_lifecycle=0&p_p_state=normal&p_p_mode=view&_disslists_WAR_disslistsportlet_haz_detailed_concern=&_disslists_WAR_disslistsportlet_orderByCol=dte_inclusion&_disslists_WAR_disslistsportlet_substance_identifier_field_key=&_disslists_WAR_disslistsportlet_orderByType=desc&_disslists_WAR_disslistsportlet_dte_inclusionFrom=&_disslists_WAR_disslistsportlet_dte_inclusionTo=&_disslists_WAR_disslistsportlet_doSearch=&_disslists_WAR_disslistsportlet_deltaParamValue=50&_disslists_WAR_disslistsportlet_resetCur=false&_disslists_WAR_disslistsportlet_delta=200 (accessed 2023-11-16).

(9) European Chemicals Agency. *Authorisation List*. ECHA website. https://echa.europa.eu/authorisation-list (accessed 2023-11-16).

(10) European Chemicals Agency. *Authorisation process - Application for Authorisation*. ECHA website. https://echa.europa.eu/phase-3-application-for-authorisation (accessed 2024-02-21).

(11) European Chemicals Agency. *The Restriction process under REACH*. ECHA website. https://echa.europa.eu/restriction-process-phase-1 (accessed 2023-11-16).

(12) European Chemicals Agency. *Registry of restriction intentions*. ECHA website. https://echa.europa.eu/registry-of-restriction-intentions?p_p_id=disslists_WAR_disslistsportlet&p_p_lifecycle=0&p_p_state=normal&p_p_mode=view&_disslists_WAR_disslistsportlet_sbm_expected_submissionTo=&_disslists_WAR_disslistsportlet_orderByCol=diss_update_date&_disslists_WAR_disslistsportlet_substance_identifier_field_key=&_disslists_WAR_disslistsportlet_multiValueSearchOperatordiss_lec_submitter=AND&_disslists_WAR_disslistsportlet_deltaParamValue=50&_disslists_WAR_disslistsportlet_dte_withdrawnFrom=&_disslists_WAR_disslistsportlet_dte_withdrawnTo=&_disslists_WAR_disslistsportlet_prc_public_status=&_disslists_WAR_disslistsportlet_orderByType=desc&_disslists_WAR_disslistsportlet_dte_intentionFrom=&_disslists_WAR_disslistsportlet_doSearch=&_disslists_WAR_disslistsportlet_haz_scope_details=&_disslists_WAR_disslistsportlet_dte_intentionTo=&_disslists_WAR_disslistsportlet_sbm_expected_submissionFrom=&_disslists_WAR_disslistsportlet_resetCur=false&_disslists_WAR_disslistsportlet_delta=100 (accessed 2023-11-16).

(13) European Chemicals Agency. *Substances restricted under REACH*. ECHA website. https://echa.europa.eu/substances-restricted-under-reach (accessed 2023-11-16).

(14) United Nations Environment Programme. *Text of the Stockholm Convention*. https://www.pops.int/TheConvention/Overview/TextoftheConvention/tabid/2232/Default.aspx (accessed 2024-03-27).

(15) Wang, Z.; Adu-Kumi, S.; Diamond, M. L.; Guardans, R.; Harner, T.; Harte, A.; Kajiwara, N.; Klánová, J.; Liu, J.; Moreira, E. G.; Muir, D. C. G.; Suzuki, N.; Pinas, V.; Seppälä, T.; Weber, R.; Yuan, B. Enhancing Scientific Support for the Stockholm Convention's Implementation: An Analysis of Policy Needs for Scientific Evidence. *Environ. Sci. Technol.* **2022**, *56* (5), 2936–2949. https://doi.org/10.1021/acs.est.1c06120.

(16) European Commission. *Commission General Report on the Operation of REACH and Review of Certain Elements Conclusions and Actions Conclusions and Actions*; 2018. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM:2018:116:FIN (accessed 2023-11-16).

(17) European Commission. *Commission General Report on the Operation of REACH and Review of Certain Elements Conclusions and Actions - Staff Working Document*; 2018. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=SWD%3A2018%3A58%3AFIN (accessed 2023-11-16).

(18) European Commission. *Chemicals strategy for sustainability*. European Commission website. https://environment.ec.europa.eu/strategy/chemicals-strategy_en (accessed 2023-11-16).

(19) European Commission. *Background Paper Authorisation and Restrictions Workshop*; 2021; p 19. https://single-market-economy.ec.europa.eu/system/files/2021-11/Background%20paper%20authorisation%20and%20restrictions%20workshop%2012%20Nov_FINAL.docx.pdf (accessed 2023-11-16).

(20) United Nations. *The Montreal Protocol on Substances that Deplete the Ozone Layer*. Ozone Secretariat website. https://ozone.unep.org/treaties/montreal-protocol (accessed 2023-11-16).

(21) United Nations. *Decision IV/25 in the Montreal Protocol: Essential uses*. https://ozone.unep.org/treaties/montreal-protocol/meetings/fourth-meeting-parties/decisions/decision-iv25-essential-uses?q=fr/meetings/fourth-meeting-parties-montreal-protocol/decisions/decision-iv25-utilisations-essentielles (accessed 2023-11-16).

(22) T. Cousins, I.; Goldenman, G.; Herzke, D.; Lohmann, R.; Miller, M.; A. Ng, C.; Patton, S.; Scheringer, M.; Trier, X.; Vierke, L.; Wang, Z.; C. DeWitt, J. The Concept of Essential Use for Determining When Uses of PFASs Can Be Phased Out. *Environ. Sci. Process. Impacts* **2019**, *21* (11), 1803–1815. https://doi.org/10.1039/C9EM00163H.

(23) T. Cousins, I.; Witt, J. C. D.; Glüge, J.; Goldenman, G.; Herzke, D.; Lohmann, R.; Miller, M.; A. Ng, C.; Patton, S.; Scheringer, M.; Trier, X.; Wang, Z. Finding Essentiality Feasible: Common Questions and Misinterpretations Concerning the "Essential-Use" Concept. *Environ. Sci. Process. Impacts* **2021**, *23* (8), 1079–1087. https://doi.org/10.1039/D1EM00180A.

(24) Directorate-General for Environment (European Commission); WSP Environment & Infrastructure Solutions; Bougas, K.; Flexman, K.; Keyte, I.; Corden, C. *Supporting the Commission in Developing an Essential Use Concept*; Publications Office of the European Union: LU, 2023.

(25) Dalglish, S. L.; Khalid, H.; McMahon, S. A. Document Analysis in Health Policy Research: The READ Approach. *Health Policy Plan.* **2020**, *35* (10), 1424–1431. https://doi.org/10.1093/heapol/czaa064.

(26) United Nations Environment Programme. *The New POPs under the Stockholm Convention*. Stockholm Convention website. https://chm.pops.int/?tabid=2511 (accessed 2023-11-16).

(27) European Chemicals Agency. *Main alternatives to harmful substances subject to REACH authorisation*. ECHA website. https://echa.europa.eu/alternatives-to-harmful-substances-subject-to-authorisation (accessed 2023-12-13).

(28) Roy, M. A.; Cousins, I.; Harriman, E.; Scheringer, M.; Tickner, J. A.; Wang, Z. Combined Application of the Essential-Use and Functional Substitution Concepts: Accelerating Safer Alternatives. *Environ. Sci. Technol.* **2022**, *56* (14), 9842–9846. https://doi.org/10.1021/acs.est.2c03819.

(29) Tickner, J. A.; Schifano, J. N.; Blake, A.; Rudisill, C.; Mulvihill, M. J. Advancing Safer Alternatives Through Functional Substitution. *Environ. Sci. Technol.* **2015**, *49* (2), 742–749. https://doi.org/10.1021/es503328m.

(30) van Dijk, J.; Figuière, R.; Dekker, S. C.; van Wezel, A. P.; Cousins, I. T. Managing PMT/vPvM Substances in Consumer Products through the Concepts of Essential-Use and Functional Substitution: A Case-Study for Cosmetics. *Environ. Sci. Process. Impacts* **2023**, *25* (6), 1067–1081. https://doi.org/10.1039/D3EM00025G.
(31) Figuière, R.; Borchert, F.; Cousins, I. T.; Ågerstrand, M. The Essential-Use Concept: A Valuable Tool to Guide Decision-Making on Applications for Authorisation under REACH? *Environ. Sci. Eur.* **2023**, *35* (1), 5. https://doi.org/10.1186/s12302-022-00708-x.
(32) European Chemicals Agency. *Restriction on the manufacture, placing on the market and use of PFASs*. https://echa.europa.eu/registry-of-restriction-intentions/-/dislist/details/0b0236e18663449b (accessed 2024-03-27).

Supporting Information

S1. Data collected

See separate Microsoft Excel file.

Table S1.1 – Main reasons for granting exemptions under the Stockholm Convention (with quotes from POPRC)[26]

Table S1.2 – Main reasons for granting derogations under the REACH Restriction process (with quotes from SEAC)[12]

Table S1.3 – Overview of the applications for authorisation received under the REACH Authorisation process[27]

S2. Essential-use concept criteria according to WSP (2023)

The tables S2.1 and S2.2 list the criteria that a use of a substance of concern should fulfil to be considered as “necessary for health and safety” and “critical for the functioning of society” (respectively) according to the latest essential-use concept framework proposed by WSP.

Table S2 1 Criteria for considering a use as "necessary for health and safety"[24]

Criteria	Additional information
Preventing, monitoring or treating severe health issues	Uses may include those in medical devices, pharmaceuticals, healthcare, or other health-related uses, directly linked to the prevention, monitoring, or treatment of severe health issues. Mental illness should be included in "severe health issues" if patients affected by psychological problems have their abilities to engage in functional and occupational activities severely impaired
Sustaining basic conditions for human life and health	"Basic conditions for human health and life" include food, water, and shelter/security. Environmental health can be included here (e.g. if use to prevent air pollution)
Managing and preventing health crises and emergencies	E.g. Human health disease outbreak
Personal safety	Proper functioning of products/processes where the purpose of the chemical/product/process is to ensure personal safety (e.g. PPE, seatbelts, fire resistance products)
Public safety	Safety of public infrastructure (e.g. road safety, public building safety) as well uses required to ensure the effective functioning of emergency services to prevent danger to public safety (which could include, for example, military, police, anti-terrorism, cyber security, and fire safety services).

Address a danger to animal health which cannot be contained by other means	Safeguarding animal health and welfare in line with EU standards; Prevention and control of diseases (including zoonoses) and parasites; Prevention or minimisation of suffering caused to animals or pests, for example in the case of products used for pest control.

Table S2 2 Criteria for considering a use as "Critical for the functioning of society"[24]

Criteria	**Additional info**
Providing resources or services which are critical for society	I.e. resources (e.g. raw materials) and service which must remain in service for society to function (e.g. critical infrastructure in e.g. energy and transport; waste treatments; water treatments; communication infrastructure; healthcare infrastructure)
Managing societal risks and impacts from natural and man-made crises and emergencies	E.g. repairing/preventing damages to infrastructure in case of natural disaster
Protecting cultural heritage	"Cultural heritage" can be understood as (i) monuments, (ii) groups of buildings, (iii) sites.
Running traditional and religious practices	Applied in a similar way than in the Minamata Convention
Protecting and restoring the natural environment	E.g. To reduce emissions of greenhouse gases or biodiversity losses; for analysis and monitoring of pollutants; for remediation of pollutants in the environment

S3. Background information the restriction dossier of intentionally added microplastics

In the restriction dossier, “microplastics” have been identified as *“small, usually microscopic, solid particles made of synthetic polymer”* which are associated with a long-term persistence in the environment as they are resistant to (bio)degradation. According to the dossier submitter, microplastics represent a concern for the environment and human health because: (i) they are small, which makes them available for ingestion and which increase their potential to be transferred along the food chain; (ii) they are very resistant to (bio)degradation, which result in microplastics being present in the environment for a long time after their release; (iii) they (bio)degrade progressively into smaller particles; (iv) they are very difficult to remove from the environment after release, which makes the microplastics pollution almost irreversible; and (v) (eco)toxicological hazard have been identified either from the polymers themselves or from the impurities of additives which are contained in them.

The dossier submitter identified that the main pathways for releases to the environment are direct releases to the environment, down-the-drain, or via municipal solid waste. To face this concern, the dosser submitter proposed this restriction in order to restrict the uses of “intentionally added” microplastics. Therefore, the microplastics which are formed in the environment via (bio)degradation of larger synthetic polymer-based articles (so-called "secondary microplastics") are not included in this restriction.

During the preparation of the restriction, the dossier submitter identified a wide diversity of technical functions of microplastics in various consumer, professional and industrial products in the following type of products and use sectors: Agriculture and horticulture (in fertilisers and plant protection products); Cosmetic (both rinse-off and leave-on cosmetic products); Detergents and maintenance products; Paints, coatings and inks; Oil and gas; Construction; Medicinal products; Medical devices; and Food supplement and medical food.

In order to limit the socio-economic impacts of the restriction, the dossier submitter three different types of measures in the restriction: (i) a restriction on the placing on the market for those uses which inevitably result in releases to the environment, irrespective of the conditions of use; (ii) a labelling requirement for uses where releases of microplastics could occur if they are not used or disposed appropriately; and (iii) a reporting requirement to improve the quality of the information available.

As a result, the dossier submitter proposed that:

- the *"Polymers within the meaning of the Article 3(5) of Regulation (EC) No 1907/2006 shall not […] be placed on the market as a substance on its own or in a mixture as a microplastic in a concentration equal to or greater than [0.01] % w/w."*;
- From 18 months after the date of entry into force of the restriction, any manufacturer, importer or downstream user placing on the market a substance or a mixture containing microplastic for use derogated from the restriction shall "*ensure that the label and/or safety data sheet, where applicable, "instructions of use" and/or "package leaflet" provides […] any relevant instructions for use to avoid releases of microplastics to the environment*";
- From 12 months after the date of entry into force of the restriction, any downstream users using microplastics for uses derogated from the restriction shall "*send to ECHA […] by 31 January of each calendar year: (i) the identity of the polymer(s) used in the previous year; (ii) a description of the use of the microplastic; (iii) the quantity of microplastics used in the previous year; and (iv) the quantity of microplastics released in the environment, either estimated or measured in the previous year*".

S4. Derogations as proposed by the Dossier submitter and evaluated by SEAC

Tables S1, S2, and S3 list the derogations which have been proposed by the dossier submitter, the main reason for such a proposal and the conclusion of SEAC. Within the restriction, the dossier submitter proposed six derogations from the whole restriction (Table S1); seven derogations from the ban only but for which the labelling requirements and mandatory reporting still apply (Table S2); and seven uses for which the dossier submitter proposed to set a date of entry into force later than the rest of the restriction (Table S3).

As illustrated in Figure 1, seven of these derogations were recommended either because no alternatives for the specific use were identified, or because the specific sector would not be able to fully implement the alternative before the initial date of entry into force, and it would need more time for the transition.

One derogation was proposed for the industrial uses of microplastics to make it clear that they are outside of the scope of this particular restriction. Three derogations were proposed for uses which are covered by other regulations (i.e. uses covered by regulations on fertilising products, on medicinal products for human or veterinary use, and on food additives). Two derogations were proposed for sludge and compost, and for food and feed as microplastics could be present as impurities, without being intentionally added to the mixture and/or product.

Six derogations were proposed for substances, mixtures and/or articles which do not contribute to the microplastic concern according to the dossier submitter, either because it does not cause harm to the environment due to its intrinsic properties (i.e. natural polymer which are not chemically modified, polymers which are (bio)degradable), and polymers with a water solubility above 2 g/L), or because it is assumed that the emissions to the environment are avoided (i.e. because microplastics are contained via technical means, or because the physical properties of the microplastics are permanently modified, or because microplastics are permanently incorporated into a soli matrix). At last, one derogation for the use on microplastics in *in vitro* diagnostic devices was proposed as the dossier submitter estimated that the releases of microplastics to the environment due to this use are very low, while the costs to substitute microplastics are rather high. Therefore, the dossier submitter assumed that the costs of implementing the restriction for this use would be too high compare to the potential benefits it would bring.

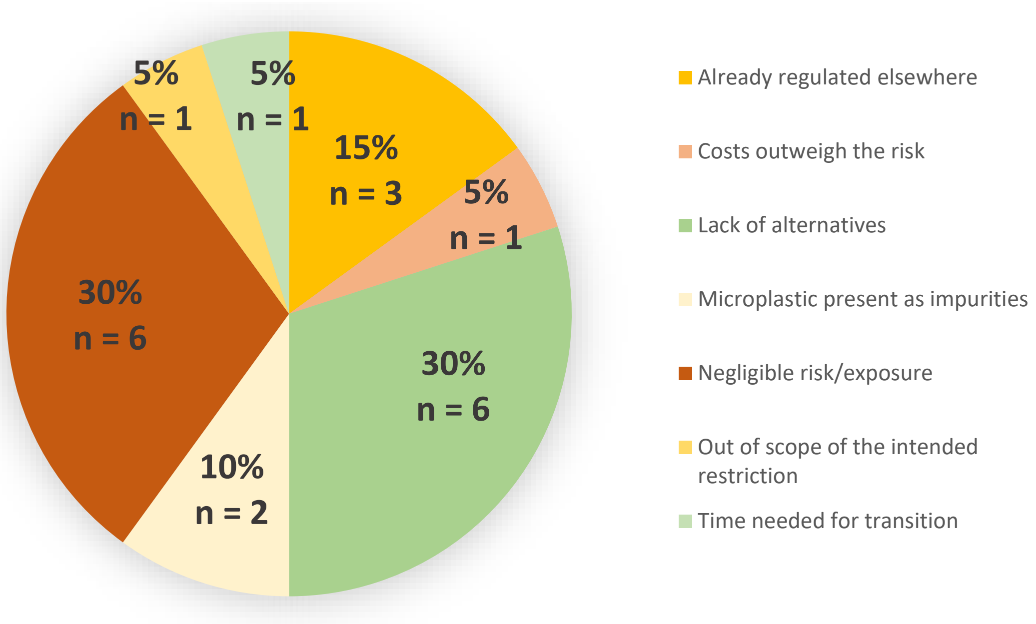

Figure S4 1 Main reasons for proposing a derogation to the restriction on intentionally added microplastics

S5. Would the essential-use concept affect the proposed derogations?

The Table S5.0 is provided in a separate Microsoft Excel file. It presents the detailed assessment of the essentiality of the uses of microplastics based on the information available in the restriction dossier.

Table S5.0 – Essentiality assessment of the uses of intentionally added microplastics

If the essential-use concept would be implemented in the REACH Restriction process in a similar way than in the Montreal Protocol, it can be assumed that a use which is necessary for health, safety and/or critical for the functioning of society and for which no safer alternatives are available could be derogated from a restriction. Following this assumption, one could wonder whether the same derogations would have been proposed by the dossier submitter of the microplastic restriction if they would have applied the essential-use concept. Table 1 lists all the derogations proposed by the dossier submitter in the microplastics restriction, the main reason for proposing such derogation, and whether such derogations would have been proposed if the essential-use concept would have been followed.

As previously explained, the dossier submitter proposed three derogations for uses and/or substances which are covered by other regulations in order to improve the implementation of the restriction and to avoid double regulations. It is likely that such type of derogations would still be proposed if the essential-use concept would be followed. Similarly, two derogations were proposed for those uses where microplastics are present as impurities in order to avoid unintended negative impacts of the restriction. It is also likely that the essential-use concept would not have changed the outcome of those derogations. One derogation was proposed by the dossier submitter to clarify that industrial uses of microplastics were not in the scope of the restriction. It is likely that such derogations would still be proposed if the essential-use concept would be implemented.

As the term “microplastics” is not defined under REACH, the dossier submitter had to determine which properties of microplastics would represent a concern. Therefore, three derogations have been proposed for polymers which are believed to not represent the same concern as microplastics to the environment. As stated in the CSS, the essential-use is meant to be applied to guide the phasing out of the most harmful substances. Hence, it is likely that such derogations would have been proposed as well to clarify that polymers would meet one of those requirements would not be considered as “most harmful substance”. Whether those criteria are enough to justify that a polymer would not be considered as a “most harmful substance” is not the focus of the present analysis.

Three derogations have been proposed by the dossier submitter and by SEAC for those uses where the releases of microplastics are expected to be negligible either because microplastics are contained by technical means to prevent releases, because they are permanently contained in a solid matrix, or because their physico-chemical properties are permanently modified. If the essential-use concept would have been applied, it is unlikely that such derogation would have been proposed. Instead, the discussion would have been focused on the essentiality of such uses. Similarly, in the particular case of the derogation for use of microplastics in IVD kits, the fact that releases of microplastics from this use are relatively small would not have weighed in the balance in the decision-making. Instead, the assessment would have focused on the essentiality of the technical function of microplastics for the IVD kits to determine whether a derogation should be proposed or not.

At last, the dossier submitter proposed seven derogations for uses for which alternatives would not be sufficiently available to replace microplastics by the date of entry into force of the restriction. Therefore, it can be assumed that those uses would have met one of the two conditions to be considered essential. If the essential-use concept would have been implemented at the time of the restriction, it is likely that the dossier submitter would have evaluated whether each of those uses are necessary for health, safety and/or critical for the functioning of society before proposing a derogation, which could have changed the outcome of the decision on the potential derogation.

Table S5 1 Derogations from the whole restriction as proposed by the dossier submitter, and with SEAC conclusion

Derogation as proposed by the dossier submitter	Main reason for derogation	Quotes (from final opinion)	SEAC conclusion
Natural polymers not chemically modified	Negligible risk/exposure	"natural polymers, as long as their chemical structure has not been chemically modified, are exempt from the restriction as they are inherently biodegradable and therefore do not contribute to the microplastics concern." p.82	Agreed
Polymers which are (bio)degradable	Negligible risk/exposure	"(bio)degradable polymers are exempt from the restriction on the basis that they do not contribute to the microplastic concern, even though they could remain in the environment for some time after use/release." p.82	Agreed
Polymers with solubility > 2g/L	Negligible risk/exposure	"including an additional derogation for water soluble polymers would improve the targeting of the restriction since soluble polymers do not contribute to the identified risk" p.100	Not assessed by SEAC, but RAC agreed
Substances or mixtures regulated under Regulation (EC) No. 2019/1009 on Fertilising Products	Already regulated elsewhere	"Complete derogation of EU regulated fertilisers from the scope of the restriction to avoid double regulation." p.82	Agreed
Sludge and compost	Microplastic present as impurities	"Complete derogation from the scope of the restriction as this was not intended to be part of the scope. Microplastics are not intentionally added into sludge and composts." p.82	Agreed
Food and feed	Microplastic present as impurities	"As these can unintentionally contain microplastics above the specific concentration limit then it is prudent to ensure that they are specifically derogated." p.82	Agreed

Table S5 2 Derogations from the ban only as proposed by the dossier submitter, and with SEAC conclusion

Derogation as proposed by the dossier submitter	Main reason for derogation	Quotes (from final opinion)	SEAC conclusion
Substances or mixtures containing microplastics used at industrial sites	Out of scope of the intended restriction	"This is required to allow continued use at industrial uses" p.82	Agreed
Medicinal products for human or veterinary use	Already regulated elsewhere	"Derogation from the scope of the restriction on use to avoid potential double regulation and any risk that the availability of medicines could be affected." p.82	Agreed
Substances or mixtures containing food additives	Already regulated elsewhere	"Derogation from the scope of the restriction on use to avoid potential double regulation, and market-distortion." p.83	Agreed
In-vitro diagnostic devices	Costs outweigh the risk	"Derogation from the scope of the restriction on use based on cost-effectiveness and socio-economic considerations." p.83	Agreed
Substances, mixtures or articles where microplastic is contained by technical means to prevent releases	Negligible risk/exposure	"Generic derogation from the restriction for uses where OC and RMM are implemented that are appropriate to adequately control the risk from the use of microplastics." p.83	Agreed

Substances, mixtures or articles where the physical properties of the microplastic are permanently modified	Negligible risk/exposure	"Generic derogation from the restriction for uses of microplastics as a substance or in a mixture where the microplastics are 'consumed' or otherwise permanently cease to exist at the point of end use" p.83	Agreed
Substances, mixtures or articles where the microplastics are permanently incorporated in a solid matrix	Negligible risk/exposure	"Generic derogation from the restriction for uses of microplastics as substances or mixtures where the microplastics are permanently 'contained' at the point of use. Permanence is intended to relate to the useful (service) life of the solid matrix, not the waste life-cycle stage." p.84	Agreed

Table S5 3 Derogations for a longer transitional period as proposed by the dossier submitter, and with SEAC conclusion

Derogation as proposed by the dossier submitter	**Main reason for derogation**	**Quotes (from final opinion)**	**SEAC conclusion**
Medical devices (where microplastics cannot be contained during end use)	Lack of alternatives	"a transition period of 6 years is considered to allow for sufficient time to reformulate and transition to alternatives." p.104	Agreed
Rinse-off cosmetic products	Time needed for transition	"Reformulations are the most important factor in this case. The typical reformulation process takes 2.5-4.5 years. Alternatives are widely available." p.105	Agreed
Detergents and maintenance products without microbeads	Lack of alternatives	"Reformulations are the most important factor in this case." p.105	Agreed
Fragrance encapsulates	Lack of alternatives	"During the Annex XV consultation industry provided information on the substitution process of microplastics in fragrance encapsulation systems, which the Dossier Submitter found may justify a longer transition period of 8 years for this use" p.105	Agreed
Agridultural & horticultural uses: Controlled release fertilisers & fertiliser additives	Lack of alternatives	"Time is required for the development of biodegradable polymers. The transitional period is intended to align with the new Fertilising	Agreed

		Products Regulation" p.106	
Agridultural & horticultural uses: Capsule suspensions PPPs & coated seeds	Lack of alternatives	"Time is required for the development of biodegradable polymers, whose functionalities might be different from products covered under the FPR"	Agreed
Leave-on cosmetic products	Time needed for transition	"Reformulations are the most important factor in this case." p.107	Agreed

Annex B: The essential-use concept: a valuable tool to guide decision-making on applications for authorisation under REACH?

Note: This annex is a copy of the open access peer-reviewed article:

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Supplementary files referred to in Annex B can be found at the Environmental Sciences Europe website referred to above and the ZeroPM Zenodo Page.

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RESEARCH **Open Access**

The essential-use concept: a valuable tool to guide decision-making on applications for authorisation under REACH?

Romain Figuière*, Flora Borchert, Ian T. Cousins and Marlene Ågerstrand

Abstract

Background In 2020, the European Commission published the Chemical Strategy for Sustainability (CSS) in which it aims to increase the level of protection for human health and the environment from hazardous chemicals. Part of the implementation of the CSS will involve a reform of the REACH authorisation and restriction processes. One option for the reform of the authorisation process is to implement the essential-use concept as a tool to guide decision-making on applications for authorisation to make the process more efficient and to align it with societal needs. The purpose of this study is to investigate whether changes in the legal text that defines the authorisation process, and of the amount and type of information that applicants should provide in an application for authorisation, are needed to enable an implementation of the essential-use concept.

Results The results suggest that no fundamental changes in the regulatory requirements are needed and that applicants should already provide sufficient and relevant information to the authorities to determine if the use(s) applied for is (are) essential.

Conclusions Although the REACH authorisation already provides a legal and practical basis for an implementation of the essential-use concept, the feasibility of the essentiality assessment and its potential to make the decision-making on applications more efficient are highly dependent on the quality of the information provided and the clearness of decision criteria. However, if an applicant successfully demonstrates that the risk related to the use(s) applied for is adequately controlled, it could not be legally justified for the European Commission to refuse an authorisation by arguing that the use(s) applied for is (are) non-essential.

Keywords Essential-use concept, Chemical Strategy for Sustainability, Authorisation process, Assessment for decision-making, REACH, Substance of Very High Concern

Background

Under the REACH Regulation (Registration, Evaluation, Restriction and Authorisation of Chemicals, EC No 1106/2006), the authorisation process aims to "*ensure the good functioning of the internal market while assuring that the risks from Substances of Very High Concern (SVHCs) are properly controlled and that these substances are progressively replaced by suitable alternative substances or technologies where these are economically and technically viable*" (Article 55). SVHCs are substances classified as persistent, bioaccumulative, and toxic (PBT), very persistent and very bioaccumulative (vPvB), carcinogenic, mutagenic, or toxic to reproduction (CMR), or of equivalent concern, such as exhibiting endocrine disruption effects [1] or resulting in increased exposure via mobility in soils/water [2]. When placing an SVHC on Annex XIV of REACH (the so-called "authorisation list"),

*Correspondence:
Romain Figuière
romain.figuiere@aces.su.se
Department of Environmental Science, Stockholm University, 10691 Stockholm, Sweden

the European Commission sets a sunset date after which the placing on the market and any uses of the substance are prohibited. However, companies can apply for continued use of the compound for a limited time by applying for authorisation, demonstrating that either the risk(s) linked to the use of the SVHC is adequately controlled, or that the socio-economic benefits of the use outweigh its risk(s) to human health and/or the environment (Article 60).

Although previous investigations by the European Commission and European Chemicals Agency (ECHA) have shown that the authorisation process enhances the substitution of SVHCs in the EU [3–5], concerns with the current implementation of the process have been identified. As indicated on ECHA's website, 26 147 substances are registered under REACH, but only 2300 substances were evaluated for compliance checks, testing proposals and/or evaluation of a potential need for further risk management in the period 2009–2021 [6]. In a roadmap on SVHCs published in 2013, the European Commission estimated that 1500 substances have known SVHC properties and committed to "*have all relevant currently known SVHCs included in the Candidate List by 2020*" [7]. However, as of 13 September 2022, only 455 substances were identified as SVHCs (for 224 entries) [8], among which only 136 are subject to authorisation (for 59 entries) [9]. This suggests that the current risk management process is too slow to properly protect human health and the environment from the risks linked to the use of SVHCs. In the second review of the REACH Regulation, the European Commission concluded that a multitude of applications for the use of small quantities of substances, information gaps, as well as unclear information in applications were responsible for long discussions and delays in decision-making [10, 11]. Therefore, the European Commission aims to improve the regulation to reach a high level of protection of human health and the environment, while reducing the administrative burden and the uncertainty for companies applying for authorisation [12].

As stated in its Chemical Strategy for Sustainability (CSS), the European Commission plans to address the identified challenges and to reform all relevant EU chemicals legislations, including the REACH authorisation and restriction processes, to increase the level of protection for human health and the environment from hazardous chemicals. In particular, the CSS aims to phase out "*the most harmful substances*" unless their use is "*necessary for health, safety or is critical for the functioning of society*" and "*if there are no alternatives that are acceptable from the perspective of human health and the environment*". So far, "the most harmful chemicals" are defined as "chemicals that cause cancers, gene mutations, affect the reproductive or the endocrine system, or are persistent and bioaccumulative [...] including those affecting the immune, neurological or respiratory systems and chemicals toxic to a specific organ", thus, more hazard classes than SVHCs as defined under REACH are covered by this definition. The European Commission further adds that the uses of "*the most harmful chemicals*" need to be essential for "*achieving a climate-neutral and circular economy*" [13].

The "essential-use concept" was first introduced in the Montreal Protocol in 1987 to phase out the use of ozone-depleting chlorofluorocarbons, except for certain "essential" uses [14]. More recently, Cousins et al. have further developed the "essential-use concept" as a tool to guide the phase-out of per- and polyfluoroalkyl substances (PFAS) [15]. The European Commission is now considering applying the essential-use concept as a tool to guide decision-making, not only on granting derogations from restrictions, but also on applications for authorisation on SVHCs [12].

As the authorisation process serves as a baseline for the industry to request derogations [12], the present study aims to analyze whether modifications in the process would be required to apply the "essential-use concept" during decision-making. The objectives are to determine (1) whether it is possible to adopt the concept within the current state of the authorisation process of the REACH Regulation; and (2) whether the information required in an application for authorisation is sufficient for assessing the essentiality of the use(s) applied for. After providing some background information on the decision-making process on application for authorisation and the "essential-use" concept, this study presents an analysis of the type of information which is being required as part of an application for authorisation following a method specifically developed for the systematic analysis of policy documents (i.e., the READ approach). The results will then be used to determine whether modifications in the Authorisation process are necessary to implement the essential-use concept to guide decision-making.

Background information on the decision-making process on applications for authorisation and the essential-use concept

Decision-making process on applications for authorisation

The Authorisation process is one of the risk management options under the REACH Regulation (EC No. 1907/2006) which aims to ensure that the risks related to the SVHC are properly controlled throughout their life cycle, and to promote the progressive substitution of SVHC with suitable alternatives. It applies to the SVHC listed in the Annex XIV of REACH (so-called "Authorisation List"). A company must submit an application for authorisation to ECHA to be able to keep using an SVHC after the sunset date. An application can be submitted for one or several use(s) of a single substance or a group of similar substances [16].

Once submitted, ECHA will check that the application conforms with the business rules and that it is complete. The application is then ready to be evaluated by the Committees for Risk Assessment (RAC) and Socio-Economic Analysis (SEAC) supported by ECHA. During the evaluation of the application, ECHA launches a public consultation for 8 weeks during which interested third parties (e.g., alternative providers, citizens, non-governmental organisations or authorities) have the possibility to provide information on possible alternative substances or technologies to the SVHC for the use(s) applied for. The Committees have the possibility to send questions to the applicant for clarification, and if necessary to organize a trialogue between the applicant, RAC and SEAC and any third party who has provided information on alternatives during the public consultation. Based on all the information received during the evaluation of the application, RAC and SEAC prepare their draft opinions on the application, within 10 months after the application has been submitted to ECHA. The RAC's opinion focuses on the risk to human health and the environment arising from the use(s) of the SVHC applied for, including the appropriateness and effectiveness of any potential risk management measures. It also can include an assessment of the risks arising from potential alternatives. The SEAC's opinion focuses on the socio-economic factors and the availability, suitability and technical feasibility of potential alternatives. The applicant has the possibility to provide comments on the draft opinions within 2 months. RAC and SEAC adopt their final opinions taking into account possible comments from the applicant within approximately 4 months after the draft opinions [16].

ECHA sends the final opinions to the European Commission, the member states and the applicant. The European Commission prepares a draft decision within 3 months after receiving the final opinions. Following the draft decision, a minimum of 3 months is needed for the vote of the REACH Committee and the subsequent adoption of the decision, including the translation [16].

The "essential-use" concept

The "essential-use" concept was introduced in 1987 in the Montreal Protocol to phase out ozone-depleting chlorofluorocarbons, except for certain "essential" uses. In the Decision IV/25, it has been agreed that a "*controlled substance should qualify as "essential" only if: (1) it is necessary for the health, safety or is critical for the functioning of society (encompassing cultural and intellectual aspects); and (2) there are no available technically and economically feasible alternatives or substitutes that are acceptable from the standpoint of environment and health*". It is also mentioned that essential uses should be permitted if all economical feasible steps have been taken to minimize the emissions of the controlled substance [14].

More recently, Cousins et al. [15] suggested to apply the "essential-use" concept to guide the phase-out of PFAS. In this study, the authors divided the uses of PFAS into three categories:

- The "non-essential" uses, which correspond to uses non-essential to health, safety, and the functioning of society. According to the authors, these uses are mainly driven by market opportunities [15];
- The "substitutable" uses, which are uses which could be considered as essential, because they perform important functions, but where alternatives that have equivalent functionality and adequate performance have been developed, which make those uses no longer essential [15];
- The "essential" uses, which are uses considered as necessary for health and safety, or other highly important purposes and for which alternatives are not yet established [15].

The authors of this study argued that the uses of PFAS should be allowed only for uses which can be considered as "essential".

In the CSS, the European Commission aims to use this approach to guide the phase-out of "*the most harmful substances*" to ensure that the chemicals are only allowed if their use is "*necessary for the health, safety or is critical for the functioning of society*" and if there are "*no alternatives available from the standpoint of human health and the environment*". At the time of this study, the European Commission is working on developing criteria to evaluate the essentiality of chemicals to ensure "*a coherent application across the EU legislation, and in particular to take into consideration the needs for achieving the green and digital transition*" [13].

Methods

The READ approach, a method specifically developed for systematic analysis of policy documents, was followed [17]. Table 1 summarizes the steps performed in this study and the steps are detailed below.

Step 1: readying the materials

In the first step of the READ approach, the documents relevant to the analysis are identified. The authorisation process under REACH is defined in the articles 55 to 66 of the Title VII of the REACH Regulation

Table 1 Analysis of policy documents following the READ approach [17]

Step 1: Readying the material	Step 2: Extraction of the data	Steps 3: Analysis of the data	Step 4: Distilling the findings
• Title VII of the REACH Regulation (EC No 1907/2006) • Annex XVI of the REACH Regulation (EC No 1907/2006)	• Legal obligations related to applications for authorisation for companies and the European Commission	• Legal requirements for a company to apply for authorisation; • Legal requirements for the European Commission to grant (or refuse) an authorisation	• To determine whether the European Commission could grant (or refuse) an authorisation based on the essentiality of the use applied for; • To determine what information companies are obliged to provide
• ECHA guidance on the preparation of an application for authorisation • ECHA guidance on the preparation of a socio-economic analysis as part of an application for authorization	• Technical function provided by the substance in the use applied for; • Necessity of the technical function for health, safety and functioning of society; • Availability of safer alternatives	• To determine if the information provided in an application for authorisation is sufficient to answer to the three key elements listed by Cousins et al. [20]	• To determine if the information asked for as part of an application for authorisation is sufficient and relevant to conclude on the essentiality of the use applied for

(EC No. 1907/2006). Furthermore, the Annex XVI of the REACH Regulation (EC No 1907/2006) specifies the type of information which should be included in a socio-economic analysis which could be part of an application for authorisation. ECHA also published two guidance documents to guide companies in preparing an application for authorisation. Therefore, the following documents were selected for analysis in this study:

1. The Title VII of the REACH Regulation (EC No 1907/2006), articles 55 to 66. It is composed of three chapters:
- Chapter 1 (Articles 55 to 59) describes the scope of the authorisation process and its requirements: the aim of the authorisation process, the conditions and the process to include a substance in Annex XIV, the implications of a substance being placed in Annex XIV, and the type of uses exempted from Authorisation;
- Chapter 2 (Articles 60 to 64) describes the conditions to grant an authorisation: the content of an application for authorisation, the procedure to reach a decision, the conditions that authorities need to take into consideration before granting an authorisation, and the conditions to review an authorisation;
- Chapter 3 (Articles 65 and 66) describes the obligations of the authorisation holder and the potential downstream users covered by the authorisation;
2. Annex XVI of the REACH Regulation (EC No 1907/2006) which describes the type of information that should be included in a socio-economic analysis within REACH;
3. The ECHA guidance on the preparation of an Application for Authorisation [18];
4. The ECHA guidance on the preparation of a socio-economic analysis as part of an application for authorisation [19].

Steps 2: extraction of the data

The second step of the READ approach consist of extracting data according to a predefined set of criteria.

The extracts from the REACH Regulation (EC No. 1907/2006) were scrutinized to determine the legal obligations of both the companies and the European Commission related to an application for authorisation. This served as a criterion for the extraction of the data from these documents.

Cousins et al. described three key elements to consider when assessing the essentiality of a use [20] which served as criteria from extracting data from the ECHA guidance documents:

1. Key element 1—Technical function: First, the precise technical function of the substance of concern and the level of technical performance it provides must be determined;
2. Key element 2—Necessity of the function for health and safety and/or functioning of society: Once the precise technical function of a substance is defined, one should assess if a loss of functionality and/or a decrease in performance would affect health, safety and/or the functioning of society;
3. Key element 3—Availability of safer alternatives: At last, to consider a specific use as essential, one should make sure that no alternatives providing a similar function and level of performance and which can be considered safer from human health and environmental perspective are available.

A first broad review of the ECHA guidance documents allowed identification of the key sections which were relevant to the objectives of the present analysis. These sections were then scrutinized by means of the three key elements suggested by Cousins et al. [20] listed above. When the ECHA guidance documents referred to one of these elements, the key information that could be useful for essentiality assessment was extracted and collected into a Microsoft Excel Spreadsheet (Microsoft Office 2016) along with its location in the document and the essential use key element it was referring to.

Step 3: analysis of the data

The third step of the READ approach consists of analyzing the extracted data. The parts extracted from the REACH Regulation were analyzed to determine what information companies are legally required to provide as part of an application for authorisation, and what information the European Commission must consider when deciding on an application. The data extracted from the ECHA guidance documents were analysed to determine whether the information that an applicant should provide in an application for authorisation is sufficient to answer to the three key elements listed by Cousins et al. for an essentiality assessment [20].

Step 4: distilling the findings

In the final step, the data from the guidance documents were analyzed and interpreted to determine if the REACH Regulation requires sufficient and relevant information from the applicants for the implementation of the essential-use concept. The data from the legal text were analyzed to determine whether the European Commission could grant (or refuse) an authorisation based on the essentiality of the use applied for.

Results

Legal requirements for a company to apply for authorisation

As specified in Article 62 of the REACH Regulation, an applicant must submit three assessment reports to ECHA when applying for authorisation:

1. A chemical safety report detailing the exposure scenario(s) and the resulting risks linked to the use(s) applied for;
2. An analysis of alternatives explaining the activities carried on by the applicant to look for potential alternatives to the SVHC for the use(s) applied for. In case alternatives to the substance are available, the applicant should explain why these alternatives are not suitable for the use(s) applied for;
3. If a suitable alternative to the substance is available, a substitution plan detailing the activities necessary to implement the alternative for the use(s) applied for, including a timeline.

In addition, applicants can submit a socio-economic analysis detailing the impacts of a refused authorisation for the use(s) applied for. As specified in Annex XVI of REACH, the regulatory authorities are responsible for providing guidance on how to prepare a socio-economic analysis, but "*the level of detail and scope [...] shall be the responsibility of the applicant for authorisation*". In short, applicants are expected to compare the impacts of a granted authorisation (so-called "continued use scenario") versus a refused authorisation (so-called "non-use scenario") on human health and the environment, the welfare of consumers, the applicant itself, and all other actors in the supply chain, as well as the wider trade, competition, and economic development. They should also consider the social implications of a granted or refused authorisation, and the social and economic impacts of using any potentially available alternative, even if they assessed it to be unsuitable for the use they are applying for [11].

Legal requirements for the European Commission to grant an authorisation

According to Article 60 of the REACH Regulation, an authorisation can be granted if "*the risk to human health or the environment from the use of a substance arising from the intrinsic properties specified in Annex XIV is adequately controlled in accordance with Sect. 6.4 of Annex I and as documented in the applicant's safety report, taking into account the opinion of the Committee for Risk Assessment [RAC]*" (so-called "adequate controlled route"). However, if it is not possible to determine a threshold to assess the risk of a substance or if the substance has been identified as PBT and/or vPvB, then an authorisation can be granted only if "*it is shown that socio-economic benefits outweigh the risk to human health or the environment arising from the use of the substance and if there are no suitable alternative substances or technologies*" (so-called "socio-economic analysis route"). It is important to note that applicants must submit a socio-economic analysis if they seek to obtain an authorisation under the socio-economic analysis route. As specified in Article 60 of the REACH Regulation, the European Commission should also consider "*whether the transfer to alternatives would result in reduced overall risks to human health and the environment*" when deciding on an application for authorisation (Additional file 1: Table S1).

Information required for an application for authorisation that could be useful for an essentiality assessment

The guidance on applications for authorisation provides recommendations to the applicants on the information that should be included in each of the three assessment reports required by the REACH Regulation. The guidance on the socio-economic analysis, as part of an application for authorisation, provides recommendations to the applicants on the information that should be included. Table 2 summarizes the information asked for in the guidance documents that could serve in an assessment of the essentiality of the use(s) applied for. The exact quotes from the guidance documents are available in Additional file 1: Table S2.

Technical function provided by the substance of concern

For the first step of an assessment of the essentiality of a use, the exact technical function provided by the substance of concern needs to be known. When applying for authorisation under the REACH regulation, the applicant should describe the use(s) applied for using the use descriptor system as developed in the

Table 2 Key information useful for an essentiality assessment that should be in an application for authorisation

Key elements for essentiality assessment	Description of the applicant's tasks and ECHA's recommendations for an application for authorisation	References
Technical function provided by the substance in the use applied for	Identification of the function of the SVHC of interest	AfA[1] (Sect. 3.4. Page 45–46)
	Explanation of if and how the final product would be affected by a change in substance/process and the use of an alternative. Consideration of implications of a lower quality of the product due to the use of an alternative substance	AfA (Sect. 3.5.1. Page 47) SEA[2] (Sect. 3.8. Page 95)
	Information on any potential customer and/or legal requirements on the end product	AfA (Sect. 3.5.1. Page 47)
Necessity of the technical function for health, safety and functioning of society	Consideration of the whole supply chain, including the production of a consumer good/service and the benefits provided by it	SEA (Sect. 2.0. and 2.2.1 Pages 30. 33 and 34)
	Comparison between the socio-economic impacts from a granted authorisation to those of a refused authorisation	SEA (Sect. 3.2.2. Page 49)
	Presentation of qualitative conclusions on the expected severity and extent of the impacts of a granted or refused authorisation in case a quantification is not possible	SEA (Sect. 2.4.2 Page 45 and Sect. 3.3.4.3. page 65)
	Qualitative health or environmental impacts from not having certain functionality (e.g., increased risk for fire accidents) due to a refused authorization	SEA (Sect. 3.3.2.1. Page 57 and Sect. 3.8 page 95)
	Evaluation of additional consumer costs and/or a loss of welfare because of a ceasing supply/decreased quality of consumer goods	SEA (Sect. 3.4.2. Page 75 and Sect. 3.5.1. Page 83)
	Consideration of the costs to the private sector and the costs to society as a whole	SEA (Sect. 3.4.1. Page 74)
	Consideration of the impacts of granted or refused authorisation on the supply chain of the available alternatives	SEA (Sect. 3.4.2. Page 79)
Availability of safer alternatives	Consideration of all types of alternatives including other manufacturers'/importers' portfolios	AfA (Sect. 3.3 Page 43 and Sect. 3.10. page 82)
	Consideration of any hazards (including physical hazards) when comparing the risk of potential alternatives. Inclusion of data contained in registration dossiers plus any relevant data that are available, including QSAR and read-across if needed	AfA (Sect. 3.7.1. and 3.7.2. Page 60–62)
	Ideally, provision of a "life cycle thinking" in the comparison of risk between alternatives	AfA (Sect. 3.7.3. Page 64)
	Consideration of using the "best available technique" framework to compare the risk of the substance to the environment (e.g., persistency) with other hazards and environmental impacts	AfA (Sect. 3.7.4.2. Page 71)
	Consideration of human health and environmental impacts of using an alternative that does not reduce the risk	SEA (Sect. 3.8. Page 94)

[1] AfA: Information taken from the ECHA Guidance on the preparation for an application for authorisation [18]

[2] SEA: Information taken from the ECHA Guidance on the preparation of socio-economic analysis as part of an application for authorisation [19]

guidance on information requirements and chemical safety assessment which is referred to in the two guidance documents related to the application for authorisation. This system is composed of seven different types of descriptors [21]:

1. Life-cycle stages: Provide information on the step of the substance's life-cycle, where the use takes place;
2. Sectors of use: Provide information on the sector of the economy, where the use takes place;
3. Chemical product categories: Provide information on the sectors formulating mixtures, and on the types of product used by end-users (which could be industrial, professional, or consumer end-users);
4. Process categories: Define the tasks, or process types from the occupational perspective;
5. Environmental releases categories: Describe the characteristics of a use from the environmental perspectives based on the life-cycle stage, where the use takes place, the technical fate of the substance resulting from the use, whether the use takes place indoors or outdoors, and indication on whether articles are used under release-promoting conditions, or where the releases of the substances are intended;
6. Article categories: Describe the type of articles, where the substance is contained, or on which it has been applied.
7. Technical function: Describes the role the substance fulfils when it is used.

The list of possible options for each descriptor type as developed by ECHA in the guidance on the use descriptor system is provided in the Annex R.12.4. of the ECHA guidance on the information requirements and chemical safety assessment [21]. Taken all together, these use descriptors allow for a proper understanding of the type of use applied for. Furthermore, ECHA encourages applicants to "*develop the description further to specify more precisely what use is applied for*" [18]. Furthermore, applicants are required to provide information on the function provided by the substance of interest, in the analysis of alternatives and/or the chemical safety report as part of an application for authorisation. In the guidance, ECHA recommends applicants (in particular manufacturers and importers) to consult their downstream users to properly understand the precise function of the SVHC, but also to identify potential alternatives available by consulting stakeholders outside of their supply chain. Applicants should document any specific customer and/or legal technical requirements they need to comply with to better understand the level of performance that any potential alternative should fulfill [18].

Necessity of the function for health, safety and/or functioning of society

A use would be deemed "essential" if the function of the substance of concern is necessary for the health, safety and/or the functioning of society. When applying for authorisation under the REACH regulation, applicants are expected to evaluate how the final products would be affected if there are changes in the process following the implementation of an alternative as "*the main socio-economic benefits of continued use are likely to come from the end-use rather than from each intermediate use*" [19]. Hence, applicants are expected to include the whole supply chain of the substance, from the manufacturing of the raw materials of the SVHC to the consumer goods or services when determining the scope of the socio-economic analysis. By doing so, they can assess whether the end product or service would lose a certain functionality and/or would decrease in quality in case of a refused authorisation. The implications of such a loss should be described in the socio-economic analysis by evaluating if consumers would face additional costs or a loss of welfare. In addition, they should consider whether there would be any impacts on human health and/or the environment that would result from this loss (e.g., increased risk of fire accident) [19].

When evaluating the economic feasibility of an alternative, applicants should not only focus on the costs necessary to implement the alternative but they should also consider the potential changes in revenues caused by the alternative [18]. If the alternative is available in general, ECHA also recommends including the economic and social impacts likely to occur in the supply chain of the alternative in the socio-economic analysis. At last, applicants should consider the costs to society in general in addition to the costs to the private sector when estimating the economic impacts of each scenario [19].

Availability of safer alternatives

The use of a substance of concern would be considered "essential" only if there are no alternatives available that provide a similar function and level of performance, and which can be considered safer from a human health and environmental perspective. When applying for authorisation applicants are expected to explain why there are no suitable alternatives available for the use applied for at the time of the application. In the guidance, ECHA defines a suitable alternative as an alternative "*which is safer (i.e. entailing a lower risk for human health or the environment) and technically and economically feasible in the EU (i.e. not in abstract or in laboratory conditions or under conditions that are exceptional). Furthermore, it must be available from the perspective of production* *capacities of alternative substances, or the perspective of the feasibility of the alternative technology, and in light of the legal and factual requirements for putting them into circulation*" [18]. Therefore, applicants are expected to compare the risk of the alternatives with the initial substance to ensure that implementing the alternative would indeed reduce the risk to human health and the environment. It is important to note that applicants are not expected to produce new toxicity data on the considered alternatives, but should rely on the data available to them. They should collect (eco)toxicological data on all relevant hazard endpoints (including physical hazards) not only from the ECHA registration database but also from other publicly available databases and open scientific literature. If no experimental data are available, ECHA recommends the applicants to use QSAR models and a read-across approach to assess the hazards of an alternative. Applicants should also compare the (eco)toxicity hazards with other types of environmental impacts (e.g., energy use, carbon emissions) and at a different stage of the life cycle of the alternative to ensure that the switch to the alternative would not result in a regrettable substitution [18]. If an applicant expects that a refused authorisation would result in the implementation of a non-suitable alternative from a risk perspective, the impacts on human health and/or the environment from using this alternative should be assessed in the socio-economic analysis [19].

Figure 1 summarises how the information required as part of an application for authorisation could be used for an essentiality assessment of the use applied for. Overall, an application should contain relevant information to address all three key elements specified by Cousins et al. [20] to determine the essentiality of the use of a chemical substance.

Discussion

To manage a rising number of chemicals marketed in the EU and to better protect human health and the environment against the most harmful substances, the European Commission suggests to improve the current REACH authorisation by implementing the essential-use concept as a potential tool to guide decision-making to make it faster, less-resource intense, and aligned with societal needs.

The information required for an authorisation should already provide sufficient and relevant information to assess the essentiality of a use by ECHA

As shown in the results section, applicants for authorisation are expected to explain the precise technical function provided by the SVHC in the use applied for, how the use of the substance influences the functionality and performance of consumer goods and/or services, if and how a decrease in functionality and/or performance

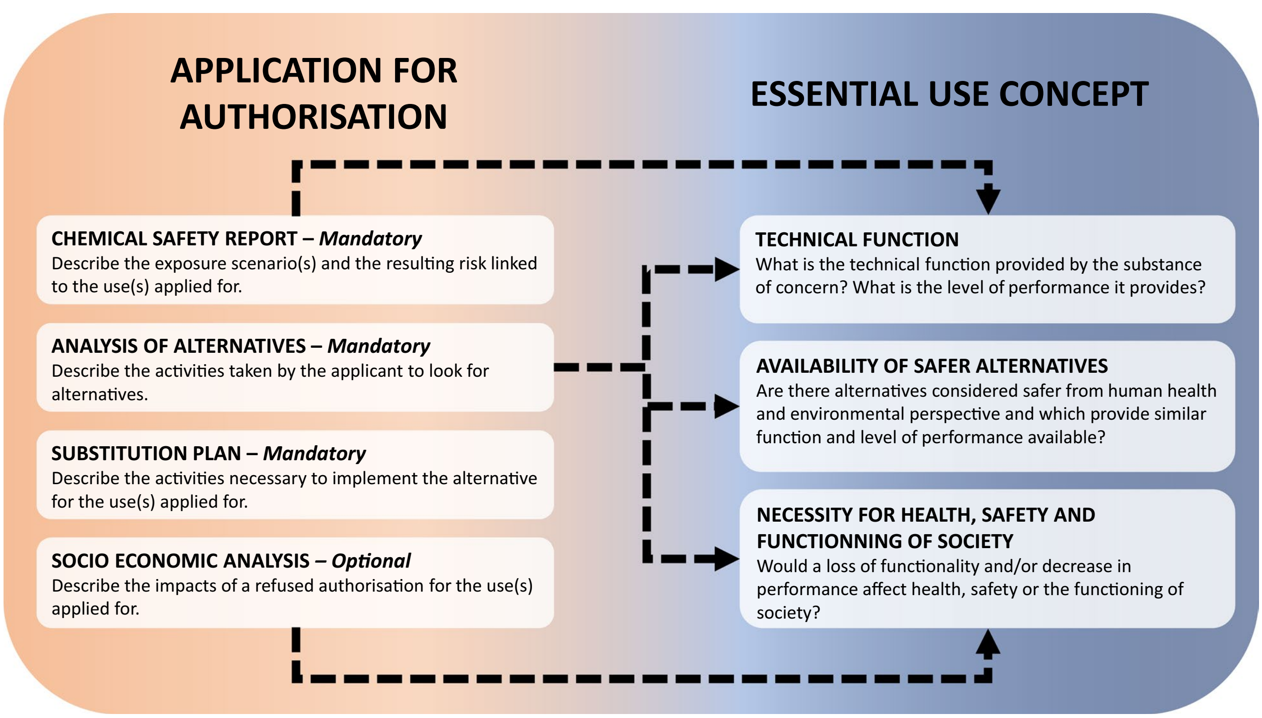

Fig. 1 Schematic showing how the information required in an application for authorisation can be used in an essentiality assessment of the use applied for

would affect consumers, and whether safer and suitable alternatives are available to the applicant. These data could be useful to the authorities to properly understand the importance of the technical function and level of performance provided by an SVHC for society, to distinguish essential end-uses from the "nice-to-have" ones, and from the "substitutable" ones. Therefore, it appears that applicants are already supposed to provide relevant information to ECHA to assess the essentiality of the use applied for, especially if they attempt to demonstrate that the socio-economic benefits of their use(s) outweigh the risks posed to human health and the environment.

Under REACH, applicants are expected to explain why there are no suitable alternative for their use(s) applied for by taking into account the technical and economic feasibility of the implementation of a potential alternative, as well as its availability. However, in the CSS, the European Commission only included the term *"...alternative that are acceptable from the standpoint of environment and health"* and did not provide its definition with respect to an essential use [13]. Considerations on the suitability of an alternative should be kept in an assessment for essentiality, as it is done under the Montreal Protocol [14]. Such discussion is important to avoid the difficult situation in which a use would be considered as non-essential, because a safer alternative exists, even though substitution is not possible in practice due to unbearable costs and/or technical issues for the implementation of the alternative.

At last, it is important to emphasize that neither the guidance documents nor the REACH legal text specify the definition and the scope of the "*socio-economic benefits*" and that "*the level of detail and scope of the socio-economic analysis [...] shall be the responsibility of the applicant for authorisation*", as specified in Annex XVI of REACH. Hence, the feasibility of an essentiality assessment of the use applied for will mainly depend on the scope and level of details of the socio-economic analysis submitted by the applicants. Further work is needed to analyze the quantity and quality of information that is contained in an application for authorisation submitted to ECHA to determine if the applicants are providing sufficient information to conclude on the essentiality of a use.

The "safe use" paradigm could hamper implementing the essential-use concept

Based on the analysis of the legal text, it appears that there are no clear legal barriers to implementing the essential-use concept to guide the decision on an application for authorisation. However, if an applicant successfully demonstrates that the risk(s) linked to the use(s) of an SVHC is (are) adequately controlled, i.e., its use is considered safe, it could not be legally justified for the European Commission to refuse an authorisation by arguing that the use applied for is non-essential (Additional file 1: Table S1), which supports previous findings recently published [22, 23]. Therefore, the relevance of an essentiality assessment for uses of SVHC for which the risks are expected to be adequately controlled could be questioned. In general, the pertinence of a "safe use" approach for the most harmful substances could be challenged. Indeed, as illustrated by the decrease of several orders of magnitude of the guideline values for some PFAS based on biological effects [24], the (eco-)toxicological safety level of other SVHCs could decrease over time if additional scientific evidence emerges and the risk would then not be adequately controlled. Furthermore, even a small continuous release of a highly persistent substance will lead to its accumulation somewhere in the environment and the eventual exceedance of a known or unknown effects threshold level, even if the risk appears controlled today [25].

Potential benefits and challenges of an essentiality assessment in the Authorisation process

Previous studies on the authorisation process have demonstrated that the socio-economic analysis attributes a relatively high weight to impacts that can be quantified and monetized (e.g., loss of profit) compared to impacts that are difficult to quantify in monetary values (e.g., social impacts, emissions of pollutants in the environment) [26, 27]. For this reason, Gabbert et al. [27] demonstrated that the current authorisation approach is not appropriate for SVHCs for which no (eco-)toxicological safety level can be determined (e.g., PBT/vPvB substances) as it does not properly consider the impacts of such chemicals on human health and the ecosystems [27]. As it is defined so far, the essential-use approach does not contain any explicit economic elements but is rather centered on social-welfare components. Therefore, it could help tackle this challenge by increasing the weight of non-monetizable impacts in the socio-economic analysis performed in an application. How, and to what extent economy-related information should be integrated into an essential-use assessment still needs to be determined. According to article 55 of REACH, "*the aim of [the authorisation process] is to ensure the good functioning of the internal market while assuring that the risks from Substances of Very High Concern are properly controlled*" (Additional file 1: Table S1). Therefore, any potential decision from the authorities made according to the essential-use concept should still consider the potential impact of a refused (or granted) authorisation on the internal market due to potential impacts on society. The main objective of the European Commission in implementing the essential-use concept in the authorisation process is to render decision-making on applications "*more efficient and aligned with societal needs*" [12]. However, the efficiency of a decision-making on the essentiality of a use applied for will also depend on the quality of the information and the amount of details provided by the applicant.

The multicriteria analysis could be the central tool for weighing qualitative and quantitative impacts in an essential-use assessment

ECHA admits that it can be difficult for the applicants to make a quantitative assessment for a certain type of impact (e.g., loss of welfare of customers), but still "*the analysis should involve quantifying and monetising impacts as far as is practicable (and appropriate) and combining the monetised results with qualitative and/or quantitative descriptions of all non-monetised impacts*". ECHA encourages applicants to present at least qualitative conclusions on the expected severity and extent of each impact in the form of a multicriteria analysis-like approach to clarify the uncertainties in their assessment and to clearly explain to authorities the assumptions they made to reach their conclusions on the evaluated impacts [19]. As described in Annex F of the guidance on socio-economic analysis, multicriteria analysis is a structured approach used to compare the impacts and/or the objectives of several alternative options. Through the measurement of indicators, such as scoring, ranking, and weighting systems, these options are often based on quantitative analysis of a wide range of qualitative and quantitative impact categories and criteria. According to ECHA, "*the key features of multicriteria analyses are the identification of criteria to provide a means of measuring the degree to which the various objectives are met, and the relative weighting of the objectives which directly incorporates their value judgments in the assessment of options. This contrasts with economic analysis (particularly the efficiency-based approaches of cost–benefit analysis and cost-effectiveness analysis) which is aimed at providing an objective measure of the net value (or social worth) of a proposed option*" [19].

Such approaches could be useful when performing a structured evaluation of the criticality for human health, safety, and/or functioning of the society of a use applied for, which could facilitate the decision-making. As already highlighted by Gabbert et al. [27], an efficient, social-welfare-oriented management of risks relies mostly on transparent and coherent decision-making [27]. To that end, regulators could develop a precise framework based on the multicriteria analysis approach with a clear definition of the minimum amount and type of information that applicants should provide. By clearly explaining to the applicants how it can be demonstrated that a use is essential and by encouraging them to be as transparent as possible on how they reach their conclusion on the essentiality of the use applied for, it can be expected that regulatory authorities will be able to reach a reliable decision faster and less resource-intense. The potential novel framework should be illustrated with concrete examples to explain how authorities would decide on an application for authorisation based on the quantity and quality of the information provided, so the outcome of the process could be more predictable for the applicants. A more detailed description of information requirements for an essential-use assessment within an application for authorisation would be needed to ensure the workability and predictability of this novel risk management approach.

Conclusions

This study emphasizes that no major changes in the current authorisation process are needed to implement the essential-use concept as a tool to guide decision-making. However, if an applicant successfully demonstrates that the risk related to the use(s) applied for is adequately controlled, it could not be legally justified for the European Commission to refuse an authorisation by arguing that the use(s) applied for is (are) non-essential. More work is needed to analyze the quantity and type of information that already have been provided by applicants in the applications for authorisation. Furthermore, to reach the European Commission's objectives of making the process more efficient and less uncertain for the applicants, a clear framework based on multi-criteria analysis on how to assess the essentiality of a use should be developed. As this study is focused on the authorisation process, similar work could be done on the restriction process to determine whether the essential-use concept could guide the development and decision-making on restriction dossiers.

Abbreviations

AfA	Application for autorisation
CMR	Carcinogenic, mutagenic, toxic to reproduction
CSS	Chemicals Stragety for Sustainability
ECHA	European Chemicals Agency
PBT/vPvB	Persistent, bioaccumulative and toxic/very persistent and very bioaccumulative
PFAS	Per- and polyfluoroalkyl substances
QSAR	Quantitative structure–activity relationship
RAC	Committee for Risk Assessment
REACH	Registration, Evaluation, Authorisation and restriction of Chemicals
SEAC	Committee for socio-economic analysis
SEA	Socio-economic analysis
SVHC	Substance of Very High Concern

Supplementary Information

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Additional file 1: Table S1. Quotes extracted from the analysis of the Title VII of the REACH Regulation. **Table S2.** Quotes extracted from the analysis of the guidance on the preparation of an application for authorisation, and the guidance on the preparation of a socio-economic analysis as part of an application for authorisation.

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RF and FB designed the study. RF analyzed the data and wrote the manuscript. FB contributed to analyzing the data and writing the manuscript. All authors contributed to the discussions. All authors read and approved the final manuscript.

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Availability of data and materials
The data sets supporting the conclusions of this article are included within the article and its Additional file 1.

Declarations

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Not applicable.

Consent for publication
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Competing interests
The authors declare that they have no competing interests.

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References

1. European Chemicals Agency. Support document for identification of 4-nonylphenol, branched and linear, ethoxylated as substance of very high concern. 2013. https://echa.europa.eu/documents/10162/9af34d5f-cd2f-4e63-859c-529bb39da7ae. Accessed 09 Jan 2023.
2. European Chemicals Agency. Support document for identification of 2,3,3,3-Tetrafluoro-2-(Heptafluoropropoxy)propionic acid, its salts and its acyl halides (covering an of their individual isomers and combinations thereof) as substance of very high concern. 2019. https://echa.europa.eu/documents/10162/53fa6a5b-e95f-3128-ea9d-fa27f43b18bc. Accessed 09 Jan 2023.
3. European Chemicals Agency. Impacts of REACH restriction and authorisation processes on substitution in the European Union; 2020. https://echa.europa.eu/documents/10162/24152346/impact_rest_auth_on_substitution_en.pdf/7c95222f-5f84-57f7-4cba-65b8463c79d4. Accessed 09 Jan 2023.
4. European Commission. Impacts of REACH Authorisation. 2017. https://doi.org/10.2873/769886
5. European Chemicals Agency. Causal impacts of the REACH authorisation process on the use of substances of very high concern in the EU. 2021. https://doi.org/10.2823/415727.
6. European Chemicals Agency. Progress in evaluation. European Chemicals Agency website. https://echa.europa.eu/overall-progress-in-evaluation. Accessed 13 Sep 2022.
7. European Commission. Roadmap on substances of very high concern; 2013. https://data.consilium.europa.eu/doc/document/ST-5867-2013-INIT/en/pdf. Accessed 09 Jan 2023.
8. European Chemicals Agency. Candidate List of substances of very high concern for Authorisation. European Chemicals Agency website. https://echa.europa.eu/candidate-list-table. Accessed 13 Sep 2022.
9. European Chemicals Agency. Authorisation List. European Chemicals Agency website. https://echa.europa.eu/authorisation-list. Accessed 13 Sep 2022.
10. European Commission. Commission general report on the operation of REACH and review of certain elements conclusions and actions; 2018. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM:2018:116:FIN. Accessed 09 Jan 2023.
11. European Commission. Commission general report on the operation of reach and review of certain elements conclusions and actions—supporting documents; 2018. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=SWD:2018:58:FIN. Accessed 09 Jan 2023.
12. European Commission. Background Paper Workshop on the Reform of the REACH Authorisation and Restriction System; 2021. https://single-market-economy.ec.europa.eu/system/files/2021-11/Background%20paper%20authorisation%20and%20restrictions%20workshop%2012%20Nov_FINAL.docx.pdf. Accessed 09 Jan 2023.
13. European Commission. 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 Towards a Toxic-Free Environment; 2020. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM%3A2020%3A667%3AFIN. Accessed 09 Jan 2023.
14. United Nations. The montreal protocol on substances that deplete the ozone layer. The Montreal Protocol on Substances that Deplete the Ozone Layer. Accessed 14 Feb 2022.
15. Cousins IT, Goldenman G, Herzke D, Lohmann R, Miller M, Ng CA, Patton S, Scheringer M, Trier X, Vierke L, Wang Z, Dewitt JC (2019) The concept of essential use for determining when uses of PFASs can be phased out. Environ Sci. https://doi.org/10.1039/c9em00163h
16. European Chemicals Agency. The decision-making process on application for authorisation. https://echa.europa.eu/phase-3-application-for-authorisation. Accessed 19 Dec 2022.
17. Dalglish SL, Khalid H, McMahon SA (2020) Document analysis in health policy research: the READ approach. Health Policy Plan 35(10):1424–1431. https://doi.org/10.1093/heapol/czaa064
18. European Chemicals Agency. Guidance on the preparation of an application for authorisation; 2011. https://doi.org/10.2823/352490.
19. European Chemicals Agency. Guidance on the preparation of an application for authorisations. Guidance on the Preparation of Socio-Economic Analysis as Part of an Application for Authorisation; 2011. http://echa.europa.eu/reach_en.asp. Accessed 11 Jan 2022.
20. Cousins IT, de Witt JC, Glüge J, Goldenman G, Herzke D, Lohmann R, Miller M, Ng CA, Patton S, Scheringer M, Trier X, Wang Z (2021) Finding essentiality feasible: common questions and misinterpretations concerning the "essential-use" concept. Environ Sci Process Impacts 23(8):1079–1087. https://doi.org/10.1039/d1em00180a
21. European Chemicals Agency. Guidance on information requirements and chemical safety assessment chapter R.12 : use description, Version 3.0-December 2015; ECHA, 2015. https://echa.europa.eu/documents/10162/13632/information_requirements_r12_en.pdf/ea8fa5a6-6ba1-47f4-9e47-c7216e180197. Accessed 09 Jan 2023.
22. Montfort, J. P. (2021). The Concept of Essential Use to Regulate Chemicals: Legal Considerations. IRCL, 9. https://heinonline.org/HOL/P?h=hein.journals/icrl2021&i=14. Accessed 09 Jan 2023.
23. Garnett K, van Calster G (2021) The concept of essential use: a novel approach to regulating chemicals in the European Union. TEL. https://doi.org/10.1017/S2047102521000042
24. Post GB (2021) Recent US state and federal drinking water guidelines for per- and polyfluoroalkyl substances. Environ Toxicol Chem. https://doi.org/10.1002/etc.4863

25. Cousins IT, Ng CA, Wang Z, Scheringer M (2019) Why is high persistence alone a major cause of concern? Environ Sci. https://doi.org/10.1039/c8em00515j
26. ChemSec. Lost at SEA*; 2019. https://chemsec.org/app/uploads/2019/02/Lost-at-SEA-ChemSec-2019.pdf. Accessed 09 Jan 2023.
27. Gabbert S, Scheringer M, Ng CA, Stolzenberg HC (2014) Socio-economic analysis for the authorisation of chemicals under REACH: a case of very high concern? Regul Toxicol Pharmacol 70(2):564–571. https://doi.org/10.1016/J.YRTPH.2014.08.013

Publisher's Note

Annex C: Can the Essential Use Concept identify non-essential uses to phase out Substances of Very High Concern under REACH?

Note: This annex is currently in preparation for submission in a peer-reviewed journal. Supplementary files referred to in Annex C can be found at the ZeroPM Zenodo Page.

H2020 project Zero pollution of Persistent, Mobile substances

Identifying non-essential uses to phase out Substances of Very High Concern under REACH

Flora Borchert[1*], Romain Figuière[1], Ian T. Cousins[1], Christina Rudén[1], Marlene Ågerstrand[1]
[1] Department of Environmental Science, Stockholm University, Stockholm, Sweden
*Corresponding author: flora.borchert@aces.su.se

Abstract

The essential use concept aims to better protect consumers, vulnerable groups, and the environment from the most harmful chemicals by phasing out uses considered non-essential for society. A recent analysis suggested that the essential use concept could be integrated into the REACH authorisation procedure without major obstacles because the information required for receiving an authorisation could already be sufficient and relevant to an essentiality assessment. The aims of this study were to 1) investigate if the information provided in applications for authorisation under REACH allowed for the identification of non-essential uses, and 2) identify data gaps, challenges and potential needs for revising the assessment criteria to effectively implement the essential use concept in the REACH authorisation. In total, 100 uses were analysed. 4-(1,1,3,3-tetramethylbutyl) phenol (OPnEO) and chromium trioxide were among the most frequently used substances, covering 42 % and 35 % of the analysed uses. OPnEO was mainly used as surfactant in medical applications, and chromium trioxide was mainly used to chrome-plate metal articles for various applications. 55 % of all analysed uses were categorised as essential, while 10 % were categorised as non-essential as none of the essential use criteria were fulfilled. It suggests that it is possible to identify non-essential uses by applying the current essential use critiera. One-third (35 %) were categorised as complex. Due to the multiple purposes of the technical function and too broad information on the spectrum of end-uses, no clear categorisation could be made in these cases. Further, due to implicit wording and a list of too general examples in the essential use criteria, their interpretation was challenging. For a successful implementation of the essential use concept, we recommend the European Commission to develop guidance for applicants and refine the essential use criteria to ensure a transparent and resource-efficient authorisation procedure under REACH.

Keywords: *essential use, application for authorisation, REACH, risk management, risk assessment, SVHC, Chemical Strategy for Sustainability, Green Deal*

1. Introduction

Inspired by the Montreal Protocol from 1987, which regulates the use of ozone-depleting substances, scientists recently suggested that the so-called "essential use concept" could be applied more broadly to harmful chemicals. Following this, the European Commission announced in 2020 its ambition to prioritise phasing out the *the most harmful substances* unless their use is *essential for society* [1]–[4]. *The most harmful chemicals* are defined in the Chemicals Strategy for Sustainability Towards a Toxic-Free Environment (further the Chemical Strategy for Sustainability) as chemicals classified as carcinogenic, mutagenic, toxic to reproduction, persistent, bioaccumulative, affecting the endocrine, immune, neurological or respiratory systems, and/or toxic to a specific organ [1]. Aiming at simplifying the phase-out of these chemicals, the essential use concept is deemed to contribute to improved transparency and predictability of the regulatory process [1], [5]. In the Chemical Strategy for Sustainability, the European Commission stated that the essential use concept would be applied across all relevant regulations, including the REACH Regulation (EC 1907/2006). An ongoing discussion addresses the question of how this concept, as a novel approach to risk management, should be implemented. This discussion involves in particular consultations on how to define "essential use", estimating the impacts on regulatory processes, and which information should drive decision-making [5]–[7]. A report by WSP E&IS GmbH (further referred to as WSP), on behalf of the European Commission, aimed to further define the essential use concept and associated criteria in order to assess the feasibility of applying the concept "horizontally" across chemicals legislation in the EU [5].

Under REACH, the use of substances of very high concern (SVHCs) can be controlled under the authorisation procedure. It aims to "*ensure a good functioning of the internal market while assuring that the risks from substances of very high concern are properly controlled"*, and to progressively replace them with *"suitable alternative substances or technologies where these are economically and technically viable"* [8] (REACH Article 55). SVHCs are substances classified as carcinogenic, mutagenic or toxic to reproduction in categories 1A or 1B (CMR), persistent, bioaccumulative and toxic

(PBT), very persistent and very bioaccumulative (vPvB), or endocrine disrupting chemicals (EDCs) and chemicals of equivalent concern (REACH Article 57). Thus, they are covered by the definition of *the most harmful chemicals* (see above, [1]). If an SVHC is listed in Annex XIV of REACH, i.e. the authorisation list, a company that would like to continue using the SVHC has to apply for authorisation before a defined sunset date. This can be done either by proving that risks are well under control (adequate control route), or by showing that the socio-economic benefits of using the SVHC outweigh the risks (socio-economic route). In an obligatory assessment of alternatives and a substitution plan, the applicant has to show that there are currently no suitable alternatives available that pose a lower risk overall and that are economically and technically feasible [9]–[11].

By the time of writing, the essential use concept stipulates that the use of *the most harmful substances* would only be allowed if two criteria are met: 1) the use is "*necessary for health/safety or critical for the functioning of society*", and 2) "*there are no alternatives that are acceptable from the standpoint of environment and health*" [1]. If both criteria are met, the use would be deemed essential for society and, if the concept were to be implemented in the REACH authorisation procedure, authorisation would be granted for a limited time [5]. In comparison to the REACH authorisation, and also in contrast to the Montreal Protocol, the essential use concept, as currently stipulated in the Chemical Strategy for Sustainability, does not explicitly include economic aspects in the evaluation of essentiality.

Figuière and colleagues (2023) performed an analysis of the REACH authorisation procedure and suggested that the essentiality of a specific use could be assessed using the information already required and provided in today's authorisation process, meaning there would be no need for major changes to the existing legislation and procedures [7], [9], [10]. Since the European Commission emphasized prioritising the phase-out of the most harmful chemicals, it needs to be clarified whether the essential use concept would be capable of identifying non-essential uses. Therefore, the present analysis aimed to 1) investigate if the information provided by applicants in applications for authorisation allowed for the identification of non-essential uses, and 2) identify data gaps, challenges and potential needs for revising the assessment criteria to effectively implement the essential use concept in the REACH authorisation.

2. Method

2.1 Scope, assumptions and definitions of the essential use concept in the present analysis

In their report, WSP refined the stepwise "horizontal" approach for the decision-making on the (non-)essentiality of a use as suggested by the European Commission [5]. For the present study, the principles of their approach, as well as the described scope and assumptions made by WSP, have been applied in the context of the REACH authorisation process. A full description thereof can be found in the supplementary information section of the paper. The main aspects of the scope of, and assumptions made within, the essential use concept for the present analysis are summarised below:

- The evaluation focused on the SVHCs subject to REACH authorisation (Annex XIV), for which applications for authorisation have been submitted to the European Chemicals Agency (ECHA), as they are a sub-set of the most harmful chemicals as defined in the Chemical Strategy [1].
- The use of a SVHC is determined by its technical function to provide certain properties during an industrial process, or to products or articles resulting from that process. Only the technical function of an SVHC in the context of an application for authorisation and its potential essentiality to health/safety and/or the functioning of society is addressed in this study.
- Although only the use of an SVHC is addressed and not the SVHC or an article as such, the context of the end-use (articles, mixtures, products, processes and/or services) should be considered [5]. This can be for example a final product or article resulting from the use of an SVHC during the industrial process which is employed in the context of medical treatment but does not contain the SVHC itself.
- As one of the conditions to get an authorisation is that there are no suitable alternatives available to the applicant (Figuière et al. 2023), it has been assumed that there are no ready-to-use alternatives available to the applicants for the SVHC to replace the required technical function.

A set of essentiality criteria regarding health/safety and the functioning of society were used to analyse the selected applications for authorisation (Table 1). They were adopted from the WSP report, and are based on an analysis of existing legislation and literature, as well as consultations with relevant stakeholders [5]. In their report, WSP describes *necessary* and *critical* as the dependency of something to be achieved. In the context of an essentiality assessment, our interpretation is that the use of a SVHC could be considered essential if its technical function fulfils the criteria for essentiality [5]. This includes considering the impact of not using a certain substance, i.e. the impact of losing the technical function it provides, on health/safety or the functioning of society. According to the WSP report, other social and economic factors are not supposed to be considered when evaluating if the criteria are fulfilled (e.g. loss of jobs, impacts on a company's economy) ([5], Supplementary Information "Method" Table S2). *Necessary*, *critical* and *essential* were interpreted as synonyms in the present analysis.

Table 1. Overview of the essential use criteria and their definitions, according to the WSP report [5]. The footnotes are according to the table provided in the WSP report.

Essential use criteria	Definition
Necessity for health/safety	
Prevention, monitoring or treatment of severe health issues	The WHO definition for health: A state of complete physical, mental and social well-being and not merely the absence of disease or infirmity[1]. Any acute or chronic illness and/or health condition that carries a high risk of mortality negatively impacts the quality of life and daily function, and/or is burdensome in symptoms, treatments, or caregiver stress[2], including severe mental illness that prevents from engaging in functional and occupational activities. Risk factors linked to severe health issues, e.g. household air pollution, unsafe water, lead exposure and others listed by the Institute for Health Metrics and Evaluation/Risk Factors Collaborators under the Global Burden of Disease study[3]. Severe noncommunicable diseases[4], e.g. cardiovascular diseases, cancer, respiratory diseases and diabetes, as well as severe but less prevalent health issues, are included, too. May include uses in medical devices, pharmaceuticals, healthcare, or other health-related uses, also beyond the healthcare sector, e.g. hygiene and cleaning or physical exercise.
Sustainment of basic conditions for human life and health	Basic needs for human life and health: food and water security, adequate housing. Environmental health as a prerequisite for good human health.
Management and prevention of health crises and emergencies	Outbreaks of diseases, emergencies covered by ambulance services, etc.
Personal safety	Ensuring personal safety, e.g. the proper functioning of seatbelts, personal protective equipment (sports, workplace), bulletproof vests, life jackets, fire alarms, etc. Ensuring fire resistance in products supposed to be heated, ensuring lubrication in vehicle brakes, etc.
Public safety	Safety of public infrastructure, e.g. road safety, and public building safety, ensure the effective functioning of emergency services through e.g. military, police, anti-terrorism, cyber security, and fire safety services.

Addressing a danger to animal health which cannot be contained by other means	Safeguarding animal health and welfare according to EU standards, prevention and control of parasites/diseases (including zoonoses), pest control, prevention/minimisation of animal suffering.
Criticality for the functioning of society	
Provision of resources or services which are critical for society	Installation and maintenance of critical infrastructure which are "organisational and physical structures and facilities of such vital importance to a nation's society and economy that their failure or degradation would result in sustained supply shortages, significant disruption of public safety and security, or other dramatic consequences"[5], e.g. energy and transport, as well as waste treatment, water treatment, communication infrastructure, healthcare infrastructure, obtaining/storing critical raw materials.[6]
Management of societal risks and impacts from natural and man-made crises and emergencies	E.g. repairing/preventing damage to infrastructure from natural or man-made disasters
Protection of cultural heritage	Monuments, groups of buildings and sites that are of Outstanding Universal Value[7] from the point of view of history, art/aesthetics, science, ethnology and/or anthropology, and provide cultural diversity, social capital, collective belonging and other service.
Running of traditional and religious practices	Uses in products applied in traditional and religious practices, as in the Minamata Convention on Mercury.[8]
Protecting and restoring the natural environment	Protection and restoration of the natural environment, ecosystem services in particular, reduction of greenhouse gas emissions, biodiversity loss, analysis/monitoring/remediation of pollutants.

[1] World Health Organisation, WHO. Constitution of the World Health Organization. Accessed 2022-11-22 at: https://www.who.int/about/governance/constitution

[2] Radbruch et al., 2020. Redefining Palliative Care — A New Consensus-Based Definition. Journal of Pain and Symptom Management. 60, 754-764.

[3] The Lancet. Global Burden of Disease 2019 risk factor summaries. Accessed 2022-06-26 at: https://www.thelancet.com/gbd/summaries

[4] World Health Organization, WHO (2022). Noncommunicable diseases: Key facts. Accessed 2022-06-26 at: https://www.who.int/news-room/fact-sheets/detail/noncommunicable-diseases

[5] according to the Federal Office of Civil Protection and Disaster Assistance (BKK) of Germany, National Strategy for Critical Infrastructure Protection (KRITIS strategy). Accessed 2023-10-30 at: https://www.bsi.bund.de/EN/Themen/KRITIS-und-regulierte-Unternehmen/Kritische-Infrastrukturen/Allgemeine-Infos-zu-KRITIS/allgemeine-infos-zu-kritis_node.html

[6] European Commission. Critical raw materials. Accessed 2022-06-28 at: https://single-market-economy.ec.europa.eu/sectors/raw-materials/areas-specific-interest/critical-raw-materials_en

[7] United Nations Educational, Scientific and Cultural Organization, UNESCO (2021). Operational guidelines for the implementation of the World Heritage Convention. Accessed 2023-06-28 at: https://whc.unesco.org/en/guidelines/

[8] Accessed 2023-06-29 https://mercuryconvention.org/sites/default/files/2021-06/Minamata-Convention-booklet-Sep2019-EN.pdf

2.2 Selection of applications for authorisation for analysis under REACH

ECHA's database on *Adopted opinions and previous consultations on applications for authorisation* (https://echa.europa.eu/applications-for-authorisation-previous-consultations) was accessed on November 2nd, 2022. This database lists all applications for authorisation that were submitted for substances listed on Annex XIV, i.e. substances subject to authorisation. Information from 454 applications for authorisation that were submitted for the continued use of 30 SVHCs, were extracted into an Excel spreadsheet. From that pool, applications which contained a substitution plan were selected for analysis (n = 173). In 2020 the rules changed, and since then a substitution plan must be part of an application [11][12]. Hence, it has been assumed that the applications that include a substitution plan are the ones with the most recent and comprehensive set of information. Applications for which ECHA's Committee for Risk Assessment (RAC) and Committee for Socio-Economic Analysis (SEAC) were still developing their opinion at the time of the study were not evaluated (n = 33). Furthermore, two applications were void, or the applicants ceased their use prematurely, and one was withdrawn by the applicant. Finally, 37 applications were merged (e.g. 0143-02 and -03 were merged with 0143-01) as the applicants described similar uses of an SVHC with the same technical functions but in different applications. A final pool of 100 applications for authorisation covering 11 SVHCs was analysed (figure 1).

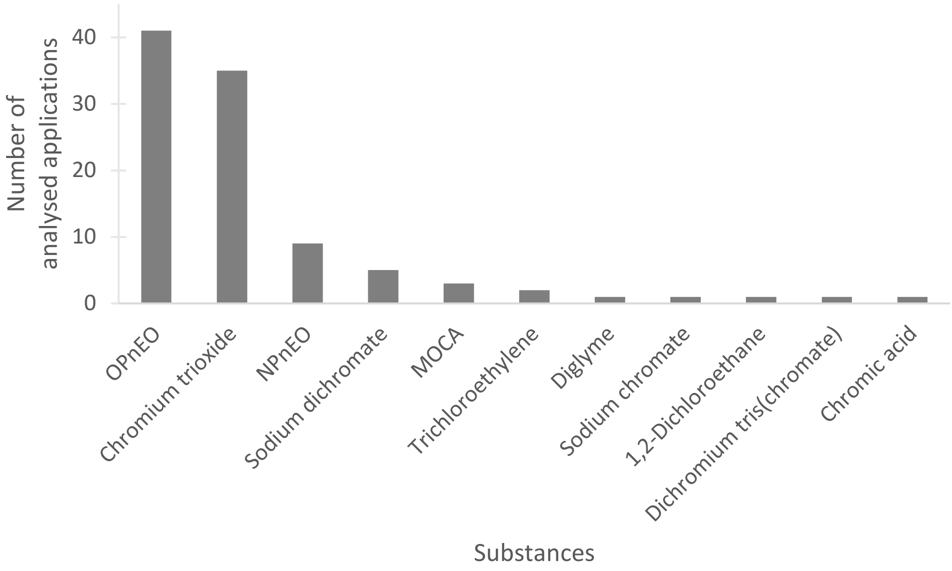

Figure 1. Overview of the 100 analysed applications for authorisation and uses of 11 SVHCs. OPnEO = 4-(1,1,3,3-tetramethylbutyl) phenol, ethoxylated, NPnEO = 4-Nonylphenol, branched and linear, ethoxylated, MOCA = 2,2'-dichloro-4,4'-methylenedianiline/4,4'-methylenebis[2-chloroaniline].

2.3 Analysis of the selected applications for authorisation

For the identification of non-essential uses, information was extracted from the following sources [9], [10]:

- Use-related descriptions and general information by the applicant displayed on ECHA's webpage of the respective application for authorisation,
- The non-confidential version of the socio-economic analysis (SEA), or joint SEA and analysis of alternatives (AoA), if available,
- Opinions on the application for authorisation by RAC and SEAC.

The detailed criteria for data collection are provided in the supplementary information "Method". All information was collected in an Excel spreadsheet (supplementary information "Data extraction").

2.3.1 Necessity of the use for health/safety and its criticality for the functioning of society

In the context of the stepwise approach suggested by WSP (section 2.1, and supplementary information), we analysed if the technical function provided by the SVHC, as described in the applications for authorisation, fulfilled the criteria for essential use as defined by WSP (table 1). Based on the collated information from the applications, in particular the socio-economic analysis part, the uses were categorized as follows:

- *Essential*: A use was categorised as "essential" if the purpose of the technical function of an SVHC for an end-use fulfilled the essential use critiera, i.e. it was covered by the technical functions defined as essential in the WSP report (table 1). For example, if the only purpose of the technical function of an SVHC used as a corrosion inhibitor was to provide drinking water safety for all end-uses (such as faucets in households), then the use would be considered to fulfil the criterion *Prevention of …[…] severe health issues: Unsafe water* and *water safety*. In such a case, it was assumed that drinking water safety would be impacted by a loss of the technical function provided by that SVHC (see section 2.2 on the definition of *essential*, *critical* and *necessary*), and, hence, the use of the substance would be considered as essential.

- *Non-essential*: In a "non-essential" use case, the purpose of the technical function of an SVHC in an end-use did not fulfil any of the essential use criteria.

- *Complex*: A use was categorised as "complex" when a decision on a category could not be made due to e.g. the (lack of) information on the purpose of the technical function(s) provided by the SVHC and/or a failure to interpret the criteria, i.e. to decide if the technical function fulfilled the WSP criteria (Table 1).

A description of these assessments is reported as free text in the supplementary information "Data extraction".

3. Results

3.1 Overall description of the analysed applications for authorisation and SVHCs

The majority of SVHCs were carcinogenic, mutagenic and/or toxic to reproduction (10/11), while two of them, OPnEO (4-(1,1,3,3-tetramethylbutyl) phenol, ethoxylated) and NPnEO (4-Nonylphenol, branched and linear, ethoxylated), were classified as endocrine disruptors. Most applications were submitted for OPnEO (42 % of 100 applications) and chromium trioxide (35 %) (figure 1). Usually, the applicants were downstream users (90 %), covering only their use of the SVHC (91%, 82/90). So-called upstream applications, in which the manufacturer, formulator or importer of the SVHC applied for the downstream use of the substance, accounted for 9 % of applications. More than one applicant was applying for authorisation in 16 % of applications. Most applicants, either alone or as a group, were located in Germany (31 %), France (18 %), Italy (14 %) and Spain (10 %). Applicants from non-EU countries were involved in 9 % of all applications. The use volumes applied for ranged from less than 1 kg (application 0161-01 OPnEO) to 3,000 kg (application 0032-03 chromium trioxide). The total sum of use volumes was approximately 9766 metric tonnes per year. For almost all applications the socio-economic route was chosen to justify continuing the use of an SVHC (98 %). The review period for which an authorisation is granted was requested by the applicants and agreed on by RAC and SEAC in 74.3 % of applications and accounted for 10.7 years on average. More information can be found in the supplementary information “Data extraction”.

3.2 Identified non-essential uses of SVHCs

In 10 applications, i.e. 10 % of those analysed, uses were categorised as non-essential (figure 2), meaning that authorisation would potentially not have been granted if our interpretation of the essential use criteria would have been applied. This proportion equals nearly 950 tonnes of non-essential uses of SVHCs, accounting for 9.7 % of the total use volume of the analysed applications. No article category was stated in 8 of the 10 uses deemed as non-essential. The substances affected were chromium trioxide (8/10) and sodium dichromate (2/10).

In these uses, chromium trioxide is used in the automotive sector to pre-treat (etch) and chrome-plate plastic articles used as interior and exterior design elements in (premium) cars, such as e.g. grilles, spoilers, internal consoles, and brand labels. The technical function of chromium trioxide is twofold.

First, as an etching agent to oxidize and roughen the plastic articles' surface. Second, it is applied as a plating agent to react with the plastic articles' surface and to provide a "*high-class surface*" (e.g. application 2018-01) of aesthetic value that is resistant to corrosion, abrasion, sunlight and chemicals. Hence, one SVHC provides different functions. It should be noted that chromium trioxide includes hexavalent chromium, which is responsible for the carcinogenic properties of the substance. However, once the chromium trioxide has reacted with the plastic surface, only elementary chromium is present. This means that the actual SVHC is not present in the final article for consumer use. Consequently, some applicants indicated that the substance would not lead to inclusion into or onto an article, hence, no article category was stated (e.g. applications 0071-01 and 0244-02). However, workers are exposed to the SVHC during industrial use. Since the technical function of chromium trioxide in these uses does not fulfil the criteria for health/safety and/or the functioning of society, these uses were categorised as non-essential.

Sodium dichromate is used as a mordant/chelating agent for the dyeing of textiles black and other dark colours, mainly wool (applications 0105-01 and 0222-01). The substance forms a complex with the dye which then attaches to the textile that is used in the fashion industry sector to produce clothes for consumer use. Through the chemical reaction, no carcinogenic hexavalent chromium is deemed to be detectable in the final product (< 0.5 mg/kg wool). The technical function is needed for aesthetic reasons to "*ensure an excellent wet fastness and a depth of tone and intensity that cannot be reached with other dye molecules*" other than chrome-based dyes to satisfy customer demands (application 0105-01). However, a description of how the technical requirements are assessed is only provided in application 0222-01 and not in 0105-01. Similar to chromium trioxide, the technical function of sodium dichromate in its uses did not fulfil the criteria for health/safety and/or the functioning of society, which is why these uses were categorised as non-essential given the assumptions made in section 2.1.

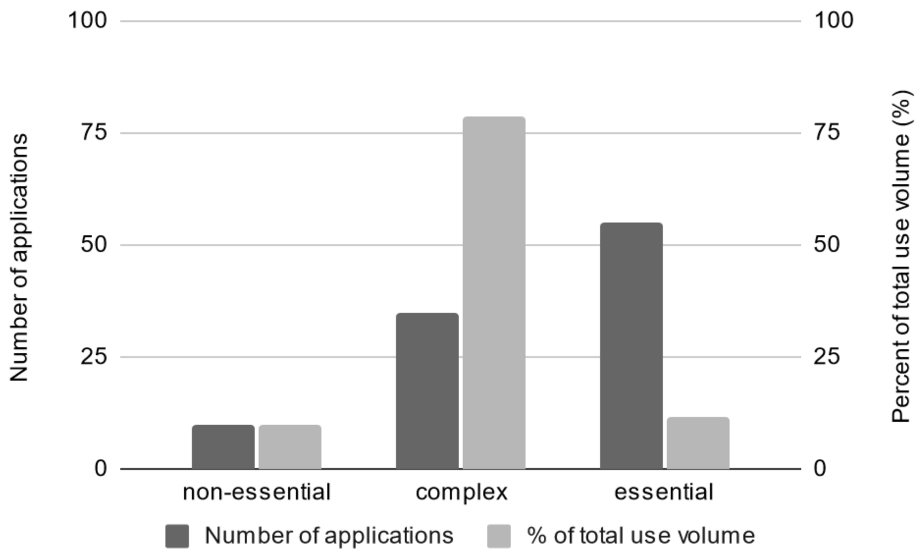

Figure 2. The dark grey bars present an overview of the numbers of applications for authorisation under REACH in which the uses applied for were categorised as non-essential (10/100), complex (35/100) or essential (56/100) according to the essential use criteria suggested in the WSP report (2023). The light grey bars indicate the use volume of each category of the total use volume in percent (%).

3.3 Identified essential uses

Uses identified as essential accounted for 55% of the analysed applications (Figure 2), with nonylphenols OPnEO (39/55) and NPnEO (9/55) accounting for 87.3 % of these. Other uses covered chromium trioxide (3/55) and sodium dichromate (2/55), as well as dichromium tris(chromate), sodium chromate, and trichloroethylene (1/55, each). Essential uses mostly had a medical context and summed up to approximately 1,132 tonnes per year, accounting for 10 % of the total use volume. Representative examples of essential uses are described in the following.

Regarding the technical function, OPnEO and NPnEO were both used either as surfactants (sometimes referred to as detergents) or emulsifiers (sometimes referred to as dispersants). Despite describing the same critical properties the technical function had to deliver, some applicants used different terms to name the technical function (e.g. "*Dispersing agent, processing aid, surfactant, stabilising agent*" in application 0186-03, "*lysing agent*" in application 0193-01, "*Cell disruption*" in application 0205-01). When used as a surfactant, the two nonylphenols lyse cell membranes, stabilise target proteins and inactivate unwanted viruses. These properties are needed in buffers or reagents applied in *in vitro* diagnostics (IVD) for the monitoring and detection of various diseases and the production of active pharmaceutical ingredients for treatment (e.g. cancer, HIV, arthritis, rare immune system or bleeding disorders, applications 0162-01, 0176-01, 0180-01, 0190-01, 0198-01), as well as for the production of vaccines (e.g. against influenza, application 0156-01) and other medicinal products (e.g. human blood for transfusions, application 0155-01). The technical function provided by OPnEO and NPnEO ensures the health safety of the end products and that they comply with medical and pharmaceutical regulations, fulfilling criterion *Prevention, monitoring or treatment of severe health issues: Uses in medical devices, pharmaceuticals, healthcare, or other health-related uses*.

The use of chromium trioxide as a corrosion inhibitor in the functional chrome plating of engine valves and valve actuation ("*lash adjusters*") is another example of an essential use based on the criteria set out in the WSP report (AfA 0228-01). The engine valves are parts of engines in passenger cars and heavy-duty engines for trucks, while the valve actuations are only parts of passenger car engines. Through the chrome plating, the applicant states that the valves can move smoothly, are wear-resistant, can endure high temperatures during engine running and ensure a higher endurance and proper functioning of the engine overall. The technical function of chromium trioxide in this use fulfilled the criteria for *personal safety* as well as *public safety* (road and transportation safety) (table 1).

In applications 0236-01 and 0136-01, sodium dichromate and sodium chromate are used as anticorrosion agents in gas absorption heat pumps. Their technical function provides resistance to corrosion for sealed circuits within the pumps, effectiveness at high operating temperatures, high functionality under high pressure and a long-lasting service of the gas absorption heat pumps. This technology is a novel heating system that is deemed to produce approximately 40 % less carbon dioxide emissions than common heating systems and to be crucial in achieving climate goals set by European governments to decarbonise the heating sector. In particular, residual buildings are deemed as the major contributors to emissions caused by heating. Hence, the technical function of sodium dichromate and sodium chromate fulfilled the criterion *Protecting and restoring the natural environment: Reduction of greenhouse gas emissions by means of reducing carbon dioxide emissions*.

3.4 Identified complex uses of SVHCs

Uses categorised as complex, i.e. they could neither be identified as non-essential nor essential uses, accounted for 35 % of the total uses. They summed up to approximately 7,685 tonnes per year, accounting for 78 % of the total use volume (figure 2). These uses were categorised as complex due to different reasons that usually occurred as a combination in a single application. It was due to both information provided in the applications as well as the framing of the criteria that posed a challenge in categorising the uses. Representative examples of complex uses are described in the following.

1) Information provided in the applications: Multiple purposes of the technical function and too broad information provided for end-uses

One reason for assigning a use to the complex category was due to the different purposes of the technical function that were both essential and non-essential. Another reason was that too broad information was provided in applications for authorisation regarding the end-uses related to the SVHC. Both reasons led to the categorisation of uses of chromium trioxide as complex, which accounted for the majority of complex cases (74.3 %, 26/35). The substance was mainly used as an etching agent of plastic or as a corrosion inhibitor on plastic and metal articles, also referred to as functional chrome-plating with decorative character (16/26, e.g. applications 0032-03, 0095-03, 0212-01, 0212-02, 0237-01). It should be noted that a couple of applications used several terms (e.g. "*Hardener/oxidising agent/colouring agent*" in application 0213-01), or a phrase ("*Ingredient used in functional chrome plating with decorative character processes to deposit metallic chromium*", e.g. applications 0095-03, 0130-01, 0131-01, 0132-01 and 0133-01) to describe the same technical function. Most applications covered sanitary equipment, but also non-sanitary articles used in the automotive (brand labels, gear lever knobs, trim strips, etc.), cosmetic (perfume caps, scissors, etc.), household (shavers, parts of coffee machines, etc.) and furniture sector (chairs, kitchen furniture, etc.), as well as white goods such as frames of washing machine doors, interior parts in fridges, and such for general engineering like electrotechnical parts, microscopes, laser optics, etc. (e.g. 0032-03, 0064-02, 0095-03, 0210-01 and 0210-03). The sanitary equipment comprised articles such as bathroom taps, shower heads, towel rails, soap dishes, and mirror frames made for consumers, public facilities and professionals. In these applications, the purpose of the technical function was to ensure drinking water safety, as sanitary articles are deemed to be in contact with drinking water, thereby fulfilling the criterion *Prevention […] of severe health issues: Unsafe water* (table 1). Due to the prevention of nickel leakage and corrosion and wear resistance provided by the chromium layer, hygiene maintenance can be assured and the sanitary equipment complies with regulations on drinking water quality. However, it was indicated that the other purpose of the technical function, as a corrosion inhibitor, was needed to produce an aesthetic and visually appealing surface according to customer demands in a broad spectrum of sanitary and non-sanitary equipment which does not fulfil the essential use criteria. First, the latter purpose (aesthetics) of the technical function does not fulfil the essential use criteria compared to its former purpose (drinking water safety), and second, the purposes of the technical function and their relation to the essential use criteria could not be assessed due to a too broad spectrum of articles (i.e. end-uses) for which the SVHC was used. In application 0032-03, the applicants noted that "*not all manufacturers and/or importers and formulators were able to identify the end-uses of their raw materials or as job platers might do chrome plating for different end-uses*" [13]. Further, the applicant commented on the draft RAC and SEAC opinion that "*[i]n upstream applications there is increased potential for uncertainty. The uncertainty is 'systemic'. SEAC itself acknowledges the problems of uncertainty such as broad uses across several industry sectors and inevitable variations in operating conditions between facilities in the draft opinion*" [13]. SEAC responded that "*SEAC agrees that uncertainties cannot be avoided in applications for authorisations. SEAC acknowledged this in its draft opinions but, additionally, highlighted the fact that some of the uncertainties present within this application are not due to the nature of applications for authorisations themselves, but rather to the approach chosen by the applicant (e.g. the broad scope, the approach for assessing economic impacts, etc.). The committees informed the applicant about these uncertainties already during the opinion-development stage*" and provided the webpage link to the guidance on uncertainty analysis [13].

Another example of a too broad and unclear end-use spectrum is the applications 0211-01, 0221-01 and 0221-02. Here, chromium trioxide or sodium dichromate was used to chrome-plate electrolytic tin plate

(ETP), also referred to as tin-plated steel, used to produce food contact material, such as cans. As a corrosion inhibitor, chromium trioxide stabilises the surface of tin-plated steel sheets by forming a stable, inert oxide layer of metallic chromium and chromium (III) oxide to ensure corrosion resistance, and thus to protect food against light, air and contaminants during storage. In case of an absence of the technical function, potential negative impacts on consumers in terms of duration of the shelf-lives and lower aesthetic quality of the food. Food safety underlies EU regulations on food contact material. However, not all of the tin-plated steel sheets are used in the food sector. The applicants indicated that 50 % ("*primarily*") of the tin-plated sheets "*are used among customers in the food packaging and processing sectors*" while non-food contact materials, such as aerosols and cans for paints, accounted for less than 5% of the tin-plated steel applications [14]. Thus, even though the technical function provides corrosion inhibition and stability to the tin-plated steel sheets to food contact materials, it was impossible to identify if the technical function was essential among the spectrum of applications of these metal sheets. It should be noted that alternative food contact materials, such as glass or plastic, as opposed to a chemical alternative to chromium trioxide, were briefly discussed in the assessment of alternatives of application 0211-01. However, this study only addressed the technical function provided by the SVHC during use and its relation to the essential use criteria. Reasons provided by the applicant for dismissing any type of potential alternatives were hence not analysed.

2) Framing of the essential use criteria: Implicit wording and a list of general examples lead to difficulties in unambiguously interpreting the essential use criteria

Another reason for categorising uses as "complex" was because of difficulties in unambiguously interpreting the essential use criteria. For example, in application 0234-02, chromium trioxide was used to chrome-plate printing and embossing cylinders, also called gravure cylinders, used in the rotogravure printing and embossing industry (functional chrome plating). The applicant supplies "*customer-specific complete plating systems for different printing segments, including packaging, decorative, publication and embossing*". They further describe that "*[r]otogravure is used primarily for long printing runs in applications such as magazines, catalogues, inserts, flyers, gift-wrap, and labels*", labels for bottles, blister packs and security printing (bank notes) as well as to produce "*packaging, wallpapers and* *floorings, among many others*" [15]. Used as a plating agent, chromium trioxide provides a scratchproof, highly wear and corrosion-resistant surface of the gravure cylinders to achieve "*fine and clear images and high printing consistency"*, making the cylinders *"resistant to oxidation, enabling the use of water as a printing ink solvent*" fulfilling customer demands [15]. Even though the function of chromium trioxide is needed to achieve the desired technical requirements, we failed to unambiguously interpret the essential use criteria as they did not cover a use scenario like this. For example, the purpose of the technical function for proper newspaper printing could fulfil the criterion *Provision of resources or services which are critical for society: Communication infrastructure* (table 1) and the labelling of bottles could fulfil the criterion *Sustainment of basic conditions for human life and health: Food security* (table 1). It was however unclear whether there was a dependency on the technical function and whether there would be substantial impacts on consumer health and the functioning of society. Further, like in other uses of chromium substances as corrosion inhibitors, the applicant adds that the corrosion resistance would benefit the sustainability and durability of the plated articles. It was left to interpretation if these two aspects could fulfil the criterion *Protecting and restoring the natural environment,* or if this was rather a side-effect of the technical function. Either way, because the applicant did not provide further data on them categorising this use as complex is also connected to the reason explained earlier.

Application 0219-01 covered the use of chromium trioxide in functional chrome-plating of cutter links of chain saws. The technical function as a plating agent ensures enhancement of the stay-sharp time of the cutter links and an easy grindability of the saws used in forestry work. Reliable equipment in forestry work might be considered indispensable for society, potentially fulfilling the criterion *Provision of resources or services which are critical for society: Obtaining critical raw materials* (Table 1). However, this or any other criterion was not sufficiently explicit to decide if it was fulfilled by this use and its technical function. It was unclear whether an absence of the technical function would have any unacceptable negative impacts on the functioning of society, i.e. whether society depends on the technical function of chromium trioxide as a plating agent on chain saw cutter links.

4 Discussion

4.1 The essential use concept, as currently suggested, is capable of identifying non-essential uses. However, one-third of the uses were categorised as "complex", hence pointing toward limitations of the concept.

In the present analysis, the essential use criteria as suggested in the WSP report were applied. According to the assumptions made and our interpretation of the criteria, 10 % of the selected uses would be categorised as non-essential. It suggests that it is possible to use the essential use criteria for identifying non-essential uses of SVHC under the REACH authorisation procedure and that potentially authorisation would not have been granted in these cases if the essential use criteria had been applied. It should be noted that the analysis reported in this paper is based on applications submitted under the current system. If the essential use criteria were to be formally applied in the authorisation process, it is possible that the applicants would further develop their arguments in favour of essentiality. Uses identified as essential accounted for 55 % of the analysed applications indicating a potential coherence between the current criteria for authorising a use under REACH and the essential use criteria.

Approximately one-third of the analysed applications were identified as complex. The insufficient information provided in the applications was one reason for that; an indication of multiple purposes of the technical function and too broad information on end-uses made it challenging to identify clearly non-essential uses. This contrasts to an analysis by Figuière and colleagues [6] who suggested that sufficient information to assess the essentiality of a use is made available due to the data requirements in REACH. Further, the complex uses emphasise that even though the essential use concept is meant to only address the use, hence technical function, of a substance and not the final product or article itself, the decision on the (non-)essentiality of a use depends on the connection between these two and is, therefore, not independent of the end-product and its use. The uses identified as complex in the present analysis show that 1) guidance is needed for applicants on how to assess the impacts of not continuing to use an SVHC on the health/safety and functioning of society, and 2) applicants need to provide additional data on the final products/articles to enable understanding of the specific purpose of the technical function of the SVHC. However, upstream applications with a broad spectrum of end-uses, can be challenging. It needs to be noted again that the present study was a retrospective analysis of existing data employing the essential use criteria. The aim was not to pinpoint poorly performed applications for authorisation but to investigate potential gaps and challenges when applying the essential use criteria. Hence, the categorisation performed in this study was based on the assumptions described above and our interpretation of the criteria.

As already mentioned in the WSP report, the essential use concept could be integrated into the REACH authorisation procedure as a complementary element to an application for authorisation, requiring companies to explicitly describe why they consider their use(s) essential without making the decision dependent on it, given the (legal) uncertainties of this novel approach to risk management [5]. This option could be a step in gaining first experiences and re-evaluating the potential benefits and challenges of that concept regarding the information provided by the applicants. It remains to be tested whether adequate guidance for the essentiality assessment could facilitate the assessments as the applicants already do crucial preparatory work within the socio-economic analysis.

Uses were categorised as complex due to a lack of clarity of the essential use criteria. Implicit wording and a list of general examples made it difficult to unambiguously interpret them. Practicability and clarity of the essential use criteria are needed to reduce subjectivity and personal bias. WSP acknowledged that criteria defined too broadly could lead to ambiguity and hence a more uncertain and less predictable procedure to identify and phase out non-essential uses. Some of the uses identified as complex exemplify that the essential use criteria were not sufficiently explicit, and thus not practicable to make a clear decision. The challenge of developing unambiguous essential use criteria, i.e. how *use*, *health*, *safety*, *functioning of society*, *essential*, *necessary*, and *critical* are defined, and their interactions evaluated, probably originates from the fact that this approach to regulating chemicals is based on more social-related values that are difficult to quantify and measure. Values are a concept of beliefs that is mainly used in disciplines like sociology, philosophy, psychology and anthropology to describe and explain social and personal organisation. Ten basic values have been recognised across cultures [16]. Extensive research has shown that these values are widely shared among different societies in different countries globally and within Europe (i.e. high within-country consensus, small in-between-country differences), suggesting that culture does not determine values [17]. Rather, the relatively consistent hierarchy of values across societies might be explained by their importance for "*a smooth functioning of significant groups or the larger society"* [16]. Mason-Renton and colleagues recommended investigating more into how values in policy for risk management could be identified, transparently communicated and incorporated into procedures [18]. In addition to that, the Joint Research Centre (JRC) of the European Commission states that a political decision that is value-motivated rather than opinion- or belief-motivated, is more supported across citizens, and that transparent decision-making is key to creating and upholding institutional trust and support [19]. Thus, understanding basic values and their relative importance to citizens can clarify the essential use criteria and reduce ambiguity when defining what technical function of a hazardous chemical in a specific use would be considered *necessary*, and/or *critical* to health, safety and the functioning of society. In doing so, it might become possible to better distinguish between *essentiality* and *benefit*/*nice-to-have.* It might also be possible to create a scale of essentiality to represent reality in the best way possible. In connection to that, what contributes to the well-being of citizens and what value citizens attach to the degree of performance of goods and services changes over time and might need to be monitored to adjust the criteria. In a recent study, EU citizen were asked about their opinions on the (non-)essentiality of uses of persistent chemicals. Uses related to personal care, household products and recreation were mostly rated non-essential, while uses related to building/construction and safety were mostly rated as essential [20]. Potentially, basic values theory could further help exploring citizen values and guide the political decision-making process on (non-)essentiality to find consent.

4.2 Use descriptions lacked consistency, calling for a revision of the current ECHA use descriptor guidance to enhance its usefulness for a coherent, transparent and protective essentiality assessment

Aligning the terminology for the technical function would add consistency and comparability of uses to the decision-making process. Often, different terms or phrases were used to describe a technical function although the purpose that the SVHC fulfilled was the same. For example, in the application 0190-01 both terms "*surfactant*" and "*emulsifier*" were used. It needs to be clarified if these technical functions differ from one another or if that is a case of inconsistent wording. In 2017, the Organisation for Economic Co-operation and Development (OECD) published a proposal on *Internationally harmonised* *functional, product and article use categories* to facilitate and harmonise the descriptions of uses which is pivotal to assessing the exposure of humans and the environment to harmful chemicals [21]. An essentiality assessment as well as the use descriptor guidance provided by ECHA could benefit from a refined description of the technical function in the different stages of a use.

In 2014, Tickner and colleagues suggested the approach of functional substitution to identify alternatives to harmful chemicals that provide the same technical function as the target substance [22]. They introduce a more sophisticated scheme to define the function of a chemical substance. The authors encourage considering three different levels of functions when trying to identify potential alternatives to a chemical of concern: (1) the chemical function, which is defined by the physico-chemical properties of the substance of interest; (2) the end-use function which describes the purpose served by the chemical function in a specific product or process; and (3) the function as a service which describes the service provided the chemical function in the specific application to society. Using this scheme, it could be evaluated if the technical performance of a certain product or process depends on the technical function provided by the substance of interest. In the present study, the descriptions of the product, article and environmental release categories according to ECHA's use descriptor system [23] did not always provide the descriptions needed to describe the full use steps and service life purposes of SVHCs for identifying non-essential uses. For example, the raw chemical chromium trioxide contains hexavalent chromium which is responsible for the carcinogenic effect of the substance. It is part of a chemical product that reacts with the surface of articles during the plating process. As soon as chromium trioxide reacts, it is reduced to elementary chromium which is not toxic *per se*. Thus, workers are at risk but not consumers as the final article does not contain the substance of concern. But to identify non-essential uses of hexavalent chromium trioxide, the final articles (e.g. sanitary equipment) that result from using the substance and that contain elementary chromium need to be considered. Thus, ECHA's use descriptor system could benefit from implementing a descriptor system of the technical function as suggested by Ticker and colleagues to more transparently describe at what stage an SVHC fulfils what purpose that links to technical requirements as well as (potentially) to health/safety and/or the functioning of society.

Further, despite considering the context of the end-use, e.g. a final article, the current analysis employed the essential use concept to applications for authorisation in a potentially narrow way, i.e. only the end-use function instead of the function as a service was considered (relating to level 2 and 3, respectively, as suggested by Tickner et al. above). However, assessing uses only at the end-use level, i.e. its function in a process or for a product/article, may not lead to an actual phase-out of that SVHC. For a reasonable protection of workers, consumers and the environment as well as possibly enhancing circularity and reducing waste, the technical function would need to be considered as a service, to assess if a system change is possible [22]. For example, even if the technical function of an SVHC in a certain article may be essential, there might be alternative articles that provide the same service as the SVHC without depending on the SVHC. This could be the case in applications 0211-01, 0221-01 and 0221-02 in which chromium trioxide or sodium dichromate were used to chrome-plate tin plates partially for the production of food contact material, such as cans. The purpose of the technical function was to ensure food safety. When considering the technical function as a service, it should be investigated if other food packaging materials could provide the same service without depending on the SVHC. Even if a use would be granted for only a limited time, the level at which the chemical function would be assessed could be pivotal for being granted a review period, hence, pivotal for the time consumers, workers and/or the environment could be exposed to an SVHC.

5 Summary and conclusions

Identifying non-essential uses could contribute to phasing out harmful substances, such as SVHCs, with the aim to protect workers, consumers, vulnerable populations and the environment from harmful exposure. According to the suggested essential use criteria, non-essential uses are uses for which health/safety and/or the functioning of society do not depend on the technical function provided by the SVHC. In this study, a pool of 100 REACH applications for authorisation was retrospectively analysed based on the essential use criteria. Following assumptions made and our interpretation of the criteria, 10 % of the uses were identified as non-essential. Examples include chromium VI substances used to plate plastic and metal articles to provide a visually appealing surface for the final article. Essential uses also accounted for approximately 10 %. These were mainly uses of the nonylphenols NPnEO and

OPnEO used as surfactants or emulsifiers for the production of pharmaceutical and medical products. Approximately one-third (35 %) of the analysed uses were categorised as complex, meaning that no clear categorisation as essential or non-essential could be made. On one hand, this pertained to the information provided in the applications for authorisation. It was challenging to clearly identify non-essential uses due to multiple purposes indicated for the technical function and too broad information on end-uses. On the other hand, categorising uses as complex stemmed from the framing of the essential use criteria. Here, implicit wording and a list of general examples posed challenges in clearly interpreting the essential use criteria. However, practicability and clarity of the essential use criteria are needed to reduce subjectivity and personal bias. The use descriptor system by ECHA had a limited benefit for describing the uses in the context of an essentiality assessment. It did not cover a description of relevant stages of a use and its technical function, e.g. the technical function needed during industrial use *versus* the technical function during consumer use. Overall, to ensure that both applicants for authorisation transparently and systematically provide the information needed for an essentiality assessment and that the criteria are clear and of sufficient detail, we recommend the European Commission and ECHA to develop technical guidance for applicants on how to apply for authorisation based on essentiality, and to further refine the essential use criteria to enhance their practicability while reducing ambiguity.

Availability of data and materials

The datasets supporting the conclusions of this article are included within the article and its additional files.

Author contributions

MÅ conceptualised the overall study. FB designed the study details, collected and analysed the data, and wrote the manuscript with contributions from all co-authors. All authors contributed to the discussions, commented on the manuscript and approved the final manuscript.

Disclosure of conflict of interest

The authors declare that they have no competing interests.

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References

[1] European Commission, "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 Towards a Toxic-Free Environment," 2020.

[2] United Nations Environment Programme, "Decision IV/25: Essential uses | Ozone Secretariat," 1992. [Online]. Available: https://ozone.unep.org/treaties/montreal-protocol/meetings/fourth-meeting-parties/decisions/decision-iv25-essential-uses?source=decisions_by_issue&args%5B0%5D=449&parent=3010&nextParent=3012. [Accessed: 09-Nov-2022].

[3] United Nations Environment Programme, "The Montreal Protocol on Substances that Deplete the Ozone Layer | Ozone Secretariat," 1987. [Online]. Available: https://ozone.unep.org/treaties/montreal-protocol-substances-deplete-ozone-layer/text. [Accessed: 12-Sep-2022].

[4] I. T. Cousins *et al.*, "The concept of essential use for determining when uses of PFASs can be phased out," *Environmental Science: Processes and Impacts*, vol. 21, no. 11. Royal Society of Chemistry, pp. 1803–1815, 01-Nov-2019.

[5] WSP E&IS GmbH, "Supporting the Commission in developing an essential use concept - Final Report," 2023.

[6] K. Garnett and G. Van Calster, "The Concept of Essential Use: A Novel Approach to Regulating Chemicals in the European Union," *Transnatl. Environ. Law*, pp. 1–29, Mar. 2021.

[7] R. Figuière, F. Borchert, I. T. Cousins, and M. Ågerstrand, "The essential-use concept: a valuable tool to guide decision-making on applications for authorisation under REACH?," *Environ. Sci. Eur.*, vol. 35, no. 1, pp. 1–12, Dec. 2023.

[8] European Commission, "Regulation on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) EC Nr. 1907/2006," no. December, 2006.

[9] ECHA, "Guidance on the preparation of socio-economic analysis as part of an application for authorisation," 2011.

[10] ECHA, "Guidance on the preparation of an application for authorisation," 2011.

[11] European Commission, “Assessment of Alternatives: Suitable Alternative Available in General & Requirements for a Substitution Plan,” 2020.

[12] ECHA, “Annual Report 2021,” 2022.

[13] ECHA, “Committee for Risk Assessment (RAC) Committee for Socio-economic Analysis (SEAC) - Opinion on an Application for Authorisation for Chromium trioxide use: Functional chrome plating with decorative character,” 2016.

[14] ECHA, “Committee for Risk Assessment (RAC) Committee for Socio-economic Analysis (SEAC) - Final Opinion on an Application for Authorisation for Use of Chromium Trioxide and Sodium Dichromate for Passivation of Electrolytic Tinplate (ETP),” 2021.

[15] Maschinenfabrik Kaspar Walter GmbH & Co. KG, “Analysis of Alternatives and Socio-Economic Analysis - Application for Authorisation for Chromium Trioxide,” 2011.

[16] S. H. Schwartz, “An Overview of the Schwartz Theory of Basic Values,” *Online Readings Psychol. Cult.*, vol. 2, no. 1, Dec. 2012.

[17] R. Fischer and S. Schwartz, “Whence differences in value priorities?: Individual, cultural, or artifactual sources,” *J. Cross. Cult. Psychol.*, vol. 42, no. 7, pp. 1127–1144, 2011.

[18] S. Mason-Renton, M. Vazquez, C. Robinson, and G. Oberg, “Science for Policy: A Case Study of Scientific Polarization, Values, and the Framing of Risk and Uncertainty,” *Risk Anal.*, vol. 39, no. 6, p. risa.13248, Dec. 2018.

[19] M. Scharfbillig *et al.*, “Values and Identities - a policymaker’s guide,” *Publ. Off. Eur. Union*, 2021.

[20] A. K. Karinen, H. Tobi, J. Devilee, A. T. De Blaeij, and S. Gabbert, “Citizens’ opinions on (non-)essential uses of persistent chemicals: A survey in seven European countries,” 2024.

[21] OECD, “INTERNATIONALLY HARMONISED FUNCTIONAL, PRODUCT AND ARTICLE USE CATEGORIES,” 2017.

[22] J. A. Tickner, J. N. Schifano, A. Blake, C. Rudisill, and M. J. Mulvihill, “Advancing safer alternatives through functional substitution,” *Environ. Sci. Technol.*, vol. 49, no. 2, pp. 742–749, Jan. 2015.

[23] European Chemicals Agency, *Guidance on information requirements and chemical safety assessment Chapter R.12 : use description, version 3.0 - December 2015.* ECHA, 2015.

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