HOW CAN THE CONCEPT OF ESSENTIAL USE DEVELOP THE EUROPEAN UNION'S REACH REGULATION OF SVHC CHEMICALS USING PFAS SUBSTANCES AS A CASE STUDY?

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DOI: https://doi.org/10.33344/vol17iss2pp64-80

Helsinki Law Review, 2/2023, pp. 64–80

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ABSTRACT

The REACH (EC, No 1907/2006 of the European and of the Council) regulation of chemicals in the European Union lacks in its agility to regulate Substances of Very High Concern (SVHC). This paper aims to give a legal-dogmatic overview of how REACH should be developed, especially in relation to SVHC chemicals, and using PFAS chemicals, or per- and polyfluoroalkyl substances, as a case study. This is done by using the "essential use" model to group SVHC chemicals in a more efficient manner.

This paper introduces PFAS chemicals and broadly SVHC substances, summarizes REACH regulations processes, and considers the feasibility of introducing "essential use" as a concept to the current regulation. The findings of this paper suggest that essential use should be developed within the restriction and authorization processes of REACH using a fast-tracked system of grouping SVHC chemicals.

1. INTRODUCTION

The regulation of chemicals requires a careful balance between socio-economic and environmental risks and benefits. Chemicals can be considered in terms of "tolerability", which refers to society's level of acceptance to withstand a certain level of risk to secure certain societal goods.[1] The use of chemicals contains a trade-off for society, as they contain risks, but also allow society to enjoy certain benefits. For example, modern medicine requires the use of harmful chemicals.[2] What is the level of risk we can tolerate? How does risk relate to the inherent benefits of using chemicals? These questions are considered under the European Union through the REACH regulation (Regulation (EC) No 1907/2006 of the European and of the Council)[3].

The REACH regulation attempts to balance risks and benefits linked to the use of chemicals within society. REACH as a regulation includes: registration, evaluation, authorization, and restrictions of chemicals.[4] REACH replaced about 40 different directives and regulations into one long singular regulation.[5] The regulation of chemicals can be considered to be an integral part of the European Union's policy on the environment, as it relates to the protection of human health and the quality of the environment.[6] REACH aims to ensure safety as well as the free circulation of substances within the internal market, leading to a dichotomy between ensuring safety and allowing for competitiveness and innovation.[7] Furthermore, REACH as a legal instrument sits within the larger context of precautionary principle, codified within Article 191(2) of the Treaty of the Functioning of the European Union, which prevents policies or actions that may cause harm to the public or to the environment if there is no scientific agreement on the possible risks.[8] Some academic opinions, however, consider that REACH in its current form is unable to adequately protect human health and the environment.

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1 Steffen Erler, *Framework for chemical risk management under REACH* (1st revised edn, Smithers Rapra Technology 2009), 4.

2 Joonas Alaranta, 'Tutkimus huolta aiheuttavien aineiden ja materiaalikierron sääntelystä REACH-asetuksen mukaan' (Dissertation in Social Sciences and Business Studies No 168, University of Eastern Finland 2018), 16.

3 Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC.

4 Susanne Kamptmann, *REACH Compliance: the Greatest Challenge for Globally Acting Enterprises* (1st ed. Wiley-VCH 2014), 1.

5 Nordic Council of Ministers, "Analysis of Enforcement According to REACH" (2006:542 published 04.03.2014) <https://www.norden.org/no/node/58578> accessed 09.09.2023, 13.

6 See the Consolidated Version of the Treaty on the Functioning of the European Union [2012] C 326/01, Art. 191(1).

7 Jessica Coria et al., "Economic Interests Could Hazard Reductions in the European Regulation of Substances of Very High Concern" [2022] 13 Nature Communications 6686, 2; See also REACH Regulation (EC) No 1907/2006, Art 1.

8 See the Consolidated Version of the Treaty on the Functioning of the European Union [2012] C 326/01, Art. 191(2).

The REACH regulation has been deemed by the Commission to be too technical, lacking in predictability, and not efficient enough in incentivizing substitutions, nor protecting the environment and health.[9] Specifically, harmful chemicals are not substituted or regulated at an efficient rate.[10] These chemicals include PFAS chemicals, or per- and polyfluoroalkyl substances, that have been found to be highly bioaccumulative and harmful to health, leading to some of these chemicals being placed on the Substances of High Concern (SVHC) list under REACH Article 55.[11] There are 200,000 substances within the European economy (in 2022), of which around 26,000 have been registered,[12] around 235 are considered as SVHC substances,[13] 59 are authorized for use,[14] and 77 are banned[15]. Identification of SVHC substances has been slower than hoped for, as the European Commission already in 2006 estimated that there are may be 1,500 substances with SVHC properties, while only a handful of them have been identified and regulated by REACH.[16] This slow pace has also allowed for the creation of substances with structural similarities than those regulated by REACH as SVHC substitutes, requiring a new process of consideration for each individual substance.[17] Therefore, the process of regulating chemicals (especially SVHCs) is not efficient enough, as many harmful substances are not registered at an efficient rate allowing for the creation of hazardous substitutes.

This paper presents an overview of how the REACH regulation can be developed to become swifter in regulating harmful SVHC chemicals in order to increase the efficiency of regulating chemicals. Specifically, using a method of grouping substances would reduce the possibility to create hazardous substitutions and speed up the process of identifying and managing SVHC substances.[18] PFAS chemicals are used as a case study of harmful chemicals to be regulated more efficiently to illustrate how substances can be grouped together to allow for a more efficient regulatory process. Academics such as Cousins et al. have developed the model of "essential

9 European Commission Directorate-General for Environment, "Supporting the Commission in Developing an Essential Use Concept: Final Report" (*Publications Office of the European Union 2023*, <https://op.europa.eu/en/publication-detail/-/publication/69d5ea0d-d359-11ed-a05c-01aa75ed71a1/language-en/format-PDF/source-283635189> accessed 09.09.2023, 89 and 92.

10 Ibid 90.

11 Ian Cousins et al., "The Concept of Essential Use for Determining when Uses of PFASs can be Phased Out" [2019] 21 Environmental Science Processes and Impacts 1803, 1804.

12 Nils Johansson, "Recycling Warning! Reconfiguring the Toxic Politics of a Circular Economy" [2022] 18 Sustainability Science 1043, 1044-5.

13 ECHA, "Candidate List of Substances of Very High Concern for Authorisation" <https://echa.europa.eu/candidate-list-table> accessed 09.09.2023.

14 ChemSafetyPro, "REACH Annex XIV: REACH Authorization List 2023" <http://www.chemsafetypro.com/Topics/EU/REACH_annex_xiv_REACH_authorization_list.html> accessed 09.09.2023.

15 ChemSafetyPro, "REACH Annex XVII: REACH Restricted List 2023" <http://www.chemsafetypro.com/Topics/EU/REACH_annex_xvii_REACH_restricted_substance_list.html> accessed 09.09.2023.

16 Daniel Slunge et al. "REACH Authorisation and the Substitution of Hazardous Chemicals: the Case of Trichloroethylene" [2022] 364 Journal of Cleaner Production 132637, 2.

17 Slunge et al. (n 16) 2.

18 Ibid 6.

use" (introduced in the Montreal Protocol on Substances that Deplete the Ozone Layer, 1987) to regulate harmful chemicals such as PFAS chemicals, while pushing for a shift in risk-based analysis by grouping substances in terms of their essentiality based on their end-use.[19] The adapted version of the concept has gained academic attention and been considered within the EU and North America.[20]

The paper specifically answers the question: *how can the concept of Essential Use develop the European Union's REACH regulation of SVHC chemicals using PFAS substances as a case study?* The paper introduces the concept in order to develop our current regulation structure, while providing an overview of the current REACH regulation on SVHCs, PFAS chemicals and the essential use concept. This paper will specifically consider PFAS chemicals as a case study, but the findings of the paper can be further applied to other chemicals that are considered to be SVHCs under the current REACH regulation. In addition, findings can be applied to create a horizontal model of essential use to be applied within regulations and directives. The methodology of the paper is legal-dogmatic, but it also produces *critical de lege ferenda* opinions of how to develop our current EU regulation. In essence, the paper aims to present a developed doctrinal system of our current regulation.

2. PFAS CHEMICALS AND THE EUROPEAN UNION'S REACH REGULATION

2.1 How are Chemicals Regulated Under the European Union?

REACH aims to protect humans and the environment by regulating chemicals. Under Article 1(1), the regulation's purpose is to ensure a "high level of protection of human health and the environment", which includes the "promotion of alternative methods of assessment of hazards of substances" and the "circulation of substances within the internal market" competitively and innovatively. In addition, under Article 1(2), REACH aims to apply the regulation on the whole lifecycle of substances. REACH is based on Article 114 of the Treaty on the Functioning of the European Union (TFEU), which provides the legal basis for competence to adopt regulation for the functioning of the internal market, which, according to 114(3), must consider environmental and consumer protection, health, and safety. Article 11 of TFEU also enshrines the overarching duty to make environmental protection "integrated into the definition and implementation" of "policies and activities" of the EU. The overarching aim of the legislation is to harmonize laws of

19 See Cousins et al 2019 (n 11).; Simona A. Balan et al. "Optimizing Chemicals Management in the United States and Canada Through the Essential Use Approach" [2023] 57 Environmental Science and Technology 1568, 1569.

20 Simona A. Balan et al. (n 19) 1569.

Member States in the form of a regulation, meaning that there is no need to transform the laws into domestic law within the European Union Member States and within the European Economic Area (including Norway, Iceland, and Liechtenstein).[21]

As mentioned, REACH as a regulation sits within the larger context of the European Union's aim to protect health and the environment, which are codified in key environmental principles. As REACH is highly technical, it is important to note that detailed environmental rules are formed from wider principles. Article 191(2) of TFEU sets four main environmental principles that guide directives and regulations: the precautionary principle (requiring risk-based analysis), the prevention principle (requiring preventative action), the rectification at source principle (rectify the environmental damage at source) and the polluter pays principle (the polluter shall pay).[22] Article 1(3) of the REACH regulation highlights the importance of the precautionary principle. The General Court has referenced the principle as a fundamental principle of EU law.[23] In addition, Article 11 of TFEU includes the integration principle, which requires that environmental protection requirements must be integrated in the definition and implementation of EU policies and actions, and in particular promoting sustainable development.[24] Legislative acts that are not compliant with the integration principle may be declared void within the Court of Justice.[25] The integration principle and precautionary principle are key in the basis of how REACH should be implemented, as environmental protection is integral in all EU policies and actions.[26] REACH as a technical regulation rests within the wider EU environmental context and has furthered the protection of health and the environment through concrete ways by establishing ECHA (European Chemicals Agency).

REACH established ECHA, based in Helsinki, to regulate chemicals within the EEA market. All manufacturers, importers, representatives and downstream users of substances must register their chemical substances under REACH to be able to include them in manufactured products within the EEA area.[27] Companies must supply registration dossiers into a database that is maintained by ECHA.[28] REACH operates on the statement: "no data, no market", which means that industry actors must prove that the chemicals they use do not harm the environment or health.[29] Kamptmann states that the provisions of the regulation signify the precautionary

21 Kamptmann (n 4) 2.
22 Suzanne Kingston et al. *European Environmental Law* (1st edn Cambridge University Press), 91.
23 Suzanne Kingston et al. (n 22) 94.
24 Suzanne Kingston et al. (n 22) 91.
25 Beate Sjåfjell, "The Environmental Integration Principle: A Necessary Step Towards Policy Coherence for Sustainability" [2018] University of Oslo Faculty of Law Legal Studies Research Paper Series No. 2018-31 1, 12.
26 Sjåfjell (n 25) 16.
27 Kamptmann (n 4) 2.
28 Erler (n 1) 68.
29 Kamptmann (n 4) 3.

principle[30], which places the chemical industry the burden to ensure chemicals are safe for humans and the environment.[31] ECHA goes through "Registration" that signifies the general obligation to submit a registration for each substance that is either manufactured or imported of 1 tonne or above each year.[32] "Evaluation" includes contemplation of dossiers, registration compliance, and substance evolution.[33] Substances of very high concern (SVHCs) will be authorized under certain conditions (within Annex XIV), while some substances may be "restricted" and prohibited (under Annex XVII).[34] Therefore, the process of risk analysis and management within REACH means that some substances are identified "*a priori* hazardous", by the European Commission, requiring restriction, phase out, or prohibition.[35] On the other hand, the majority of substances are considered to be "industrial chemicals" safe enough with some regulatory control.[36] Industry supplies a large level of data per substance that is then processed by ECHA.

2.2 How are SVHC Chemicals Regulated Under REACH?

Substances labelled as Substances of Very High Concern or SVHCs are specifically regulated under REACH. Article 55 of REACH refers to the control, replacement and finding of suitable alternatives of these substances. SVHCs are considered "persistent, bioaccumulative, and toxic (PBT), very persistent and very bioaccumulative (vPvB), carcinogenic, mutagenic, or toxic to reproduction (CMR)" or "of equivalent concern".[37] The term of "equivalent concern" is not defined in REACH, but it is a catch-all for substances that have serious effects on humans and the environment.[38]

An important example of SVHC chemicals include Per- and polyfluoroalkyl substances (PFAS). These substances have gained interest in recent years due to their impact on the environment and on human health. PFAS are a group of thousands of substances used in consumer and

30 The precautionary principle is set out in Article 191 of the Treaty on the Functioning of the European Union. As mentioned, the principle signifies that an action or policy should not be taken if there is a risk that it might cause harm to the environment or health, and there is no scientific agreement on the issue. However, action may be taken when more scientific information is available.
31 Kamptmann (n 4) 7.
32 Nordic Council of Ministers (n 5) 13.
33 Ibid, 13.
34 Nordic Council of Ministers (n 5) 14.
35 Kathleen Garnett and Geert Van Calster, "The Concept of Essential Use: a Novel Approach to Regulating Chemicals in the European Union" [2021] 10(1) Transnational Environmental Law 159, 165-6.
36 Ibid.
37 Romain Figuière et al. "The essential-use concept: a valuable tool to guide decision-making on applications for authorization under reach?" [2023] 5 Environmental Sciences Europe, 1, 1.; see also Article 57 of REACH.
38 Lucas Bergkamp and DaeYoung Park, "Key Concepts and Scope" in Lucas Bergkamp (ed.), *The European Union Reach Regulation for Chemicals: Law and Practice* (Oxford university press 2013), 55.

industrial production.[39] There are hundreds of uses for these chemicals from textile coating to food products.[40] Specifically, long-chain perfluoroalkyl acids (PFAAS) have been targeted in regulatory phase-out actions since the 2000s, as they are highly bioaccumulative, meaning that they accumulate within the environment persistently.[41] The bioaccumulation is due to their hydrophobic and oleophobic properties and C-F bonds.[42] Even shorter chain PFAS chemicals tend to accumulate over time, as they move rapidly within ground and surface waters where they may remain for centuries.[43] The use of PFAS chemicals as worded by Cousins et al. will lead to "global contamination" with "unknown consequences".[44] We do know, however, that high doses of PFAS chemicals are linked to neonatal morbidity, mortality in fetuses, developmental delays, accumulation of cholesterol, developing thyroid disease, multiple cancers, colitis and hypertension in pregnant people.[45] Therefore, these chemicals should be regulated due to their costly impact on the environment and on human health. However, as Johansson states, when limiting harmful substances, their "important economic and technical function" must also be considered.[46] Chemicals are also linked to "innovation and economic growth",[47] which means that PFAS chemicals should be considered in terms of essentiality and their trade-offs in society. It is important to note that certain PFAS chemicals are on the SVHC list, however, not all PFAS substances are SVHCs.[48]

Placing a chemical on the SVHC means that it will eventually be phased out of the internal market by a certain date. Industry can apply for extensions to the phase-out date. Extensions require (according to Article 60) that risks related to these chemicals are controlled, or socio-economic benefits outweigh the risks these pose to the environment or health.[49] The process of gaining an extension is called "authorization".[50] Authorization either requires that risks are "adequately controlled" or, if not possible to assess risk based on the scientific threshold of the substance, that the "socio-economic benefits outweigh the risks".[51] The process involves

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39 Cousins et al. (n 11) 1804.
40 Christopher Lau "Perfluorinated compounds: an Overview" in Jamie C. DeWitt (ed.), *Toxicological Effects of Perfluoroalkyl and Polyfluoroalkyl Substances* (Humana Cham 2015), 3.
41 Cousins et al. (n 11), 1804.
42 Juliane Glüge et al., "An Overview of the Uses of Per- and Polyfluoroalkyl Substances (PFAS)" [2020] 22 Environmental Science: Processes & Impacts 2345, 2346.
43 Cousins et al. (n 11), 1804.
44 Cousins et al. (n 11), 1804.
45 Lau (n 40) 9-10.
46 Johansson (n 12), 1045.
47 Ibid.
48 OECD, "Portal on Per and Poly Fluorinated Chemicals" <https://www.oecd.org/chemicalsafety/portal-perfluorinated-chemicals/countryinformation/european-union.htm> accessed 09.09.2023.
49 Figuière et al. (n 37), 2.
50 Lawrence A Kogan, "REACH and International Trade Law" in Lucas Bergkamp (ed.), *The European Union Reach Regulation for Chemicals: Law and Practice* (Oxford university press 2013) 313.
51 Figuière et al. (n 37) 5.

submitting a Chemical Safety Report, Analysis of Alternatives, Substitution Plan and potentially Socio-Economic Analysis.[52] Authorization includes an analysis by ECHA, the Committee for Risk Assessment (RAC) and Socio-Economic Analysis (SEAC).[53] During the process, an eight week public consultation is held.[54] The applicant may comment on these opinions, leading to the final opinions by RAC and SEAC, which are sent by ECHA to the European Commission, Member States and the applicant.[55] The Commission decides on the matter in three months, which is then voted on by the REACH Committee.[56] Authorization is, therefore, a highly technical process.

2.3 Current Issues with REACH

The REACH regulation has two key issues. The first issue is that the entire regulatory process of analysis is slow. Figuière et al. considers that the process is "too slow" for adequate protection of "human health and the environment".[57] The "substance-by-substance evaluation" of assessing thousands of chemicals makes it impossible for an efficient data analysis.[58] The number of hazardous substances is growing, meaning that the analysis process is growing slower.[59] Findings indicate that it takes no more than three weeks for a chemical to be introduced into the market, while officials take three to twelve years to classify a chemical as hazardous and five and a half to thirteen years to restrict and authorize a chemical use.[60] Placing a chemical on the SVHC Candidate List is found to be more efficient (with a median time of six months within the range of three months to three years).[61] However, regulation and restriction decisions vary from six months to thirteen years (median time ranging from 23 months for annex XIV inclusion and 17 months for restrictions).[62] The long process allows for the creation of chemical substitutes at a far quicker pace as compared to their regulatory processes.

This slow pace leads to the chemical industry creating "regrettable substitutes", such as in the case of the substance GenX (a PFAS) replacing PFOA.[63] GenX has been found to be similarly bioaccumulative and harmful, and has been discovered within drinking water sources in North

52 Ibid 8.
53 Ibid 3.
54 Figuière et al. (n 37) 3.
55 Ibid.
56 Figuière et al. (n 37) 3.
57 Ibid 2.
58 Garnett and Van Calster (n 35) 163.
59 Ibid, 156-6.
60 European Environmental Bureau, "EEB Analysis of the REACH and CLP Processes Timelines" <https://eeb.org/library/eeb-analysis-of-the-reach-and-clp-processes-timeliness/> accessed 10.10.2023, 2.
61 Ibid 2.
62 Ibid 3.
63 Ashley Ahearn, "A Regrettable Substitute: The Story of GenX" [2019] 1 Environmental Health Perspectives, 1, 1.

Carolina (the US).[64] The General Court confirmed in 2022 (T-636/19) that GenX is a SVHC substance, and stood by its findings on appeal in 2023.[65] Another example is the replacement of trichloroethylene (TCE) with perchloroethylene (PERC) in metal cleaning processes.[66] Slunge et al. note that the substitution of TCE to PERC provides an example of how the chemical industry can create a similar substance rapidly to one that has been phased-out, which starts the regulatory process again for a new substance and allows for use for a longer period of time.[67] They suggest that risk management should be based on grouping substances in order for similar substances to be considered together to reduce the risk of substitutes.[68] This would also allow for speed and efficiency, which is key in regulating chemicals.[69]

A second key issue with REACH is that the current processes of registration and authorization of SVHC chemicals are limited. Abelkop et al. state that there are not enough considerations of "benefits", as socio-economic benefits and substitutes are not considered in the registration process.[70] This dichotomy essentially means that the supplier of the chemical must wait a period of time (usually years) before the substance is given authorization, while being registered as SVHC and set a sunset date.[71] Therefore, a substance may be socio-economically beneficial within the European Union before its substitutes have been identified, but socio-economic analysis does not occur until authorization.[72] Academics such as Abelkop et al. conclude that registration and authorization should follow similar processes, especially since it appears that these processes were not meant to largely differ from each other by legislators, but were later amended by the European Parliament.[73] Abelkop et al. views are convincing, as the duality of the current regulation processes of SVHCs under REACH is highly technical and requires significant knowledge of the processes. These issues could be mitigated by the essential use model.

64 Ahearn (n 63), 1.
65 Case C-293/22 P *Chemours Netherlands BV v European Chemicals Agency* (ECHA) [2023] ECR 847
66 Slunge et al. (n 16) 5.
67 Slunge et al. (n 16) 5.
68 Ibid 6.
69 Ibid.
70 Adam DK Abelkop et al., "How can REACH be Improved?" in Lucas Bergkamp (ed.), *The European Union Reach Regulation for Chemicals: Law and Practice* (Oxford university press 2013), 391.
71 Ibid 391.
72 Ibid 393.
73 Ibid.

3. THE CONCEPT OF ESSENTIAL USE

3.1 History of the Concept of Essential Use

The concept of essential use was introduced during the Montreal Protocol (1987) to protect the earth's ozone layer. The concept was formally integrated into the Protocol by Decision IV/4 during the Fourth Meeting of the Protocol Parties and adopted in Decision IV/25 on essential uses in order to create a mechanism of exemption in Article 2 of the Protocol.[74] The Protocol's exemption criteria include two important points. Firstly, the use of the chemical is "necessary for health, safety or is critical for the functioning of society" and that "there are no available technically and economically feasible alternatives or substitutes" considered to be "acceptable" for health and the environment.[75] Secondly, "all economically feasible steps have been taken to minimize the essential use" and "associated emission of the substance".[76] The Protocol decisions have included a narrow definition of essential sectors.[77] Montfort considers that the Protocol targets a limited number of substances, which is not directly comparable to the REACH protocol as such.[78] Therefore, the Protocol is a useful starting point for the concept, but it must be further developed to be more specific in consideration of REACH and a wider group of substances. This has been, at least partially, done in an influential academic paper by Cousins et al, which creates a concise model of the concept.

3.2 Recent Academic Publications on the Essential Use Concept

Cousins et al. published an academic article on the concept of essential use specifically in the phase out of PFAS chemicals. The paper has been influential in shaping a theoretical understanding of how chemicals such as PFAS can be grouped together,[79] and it provides a concise view to aid in understanding a technical subject. The paper is based on the 2015 Global

74 Jean-Philippe Montfort, "The Concept of Essential Use to Regulate Chemicals: Legal Considerations" [2021] 1 ICRL, 1, 2.
75 Montfort (n 74) 2.
76 Ibid.
77 Ibid.
78 Ibid 3.
79 Mentioned in Kastalie Bougas et al, "Supporting the Commission in Developing an Essential Use Concept: Workshop Report" (Wood E&IS GmbH 2022) <https://environment.ec.europa.eu/system/files/2022-05/Essential%20Use%20Workshop%20Report%20final.pdf> accessed 09.09.2023, 7, and Garnett and Van Calster (n 35), 160 and Montfort (n 74) 7.

PFAS Science Panel's idea of regulating PFAS as a group,[80] and the concept is based on the Montreal Protocol Decision IV/25.[81] The paper outlines the essential use into a simpler form that can be applied in the phase out of PFAS chemicals. The key difference between Cousins et al.'s theory of essential use, is that within Montreal, essential use is used in prioritizing risk management, while Cousins and co-authors have formed an extended version of the concept to focus on the end use and "qualitative functions" of substances (function, need in society and environmental impact), rather than current risk management analysis.[82] The idea of the theory is to flip the current process of categorizing substances as "safe enough" or "hazardous" to considering all PFAS substances as inherently hazardous to be phased out, rather than focusing analysis on one substance at a time.[83]

Cousins et al. group chemicals based on "essential use" into three different categories: "non-essential", "substitutable" and "essential".[84] The first category ("non-essential uses") includes chemicals that are not essential for health, safety, or society, but are more "nice to have" substances, which can be diminished or "banned":[85] The second category ("substitutable uses") are important in their function, but can be replaced by other chemicals.[86] The third category includes "essential use" substances that are considered essential in their function and cannot, yet, be replaced by other chemicals.[87] The concept seeks to categorize chemicals based on their functions and essentiality, while focusing on the end use of the product the chemical is included in. Essentiality is considered by identifying the function of the substance, considering whether this function is essential for health, safety or for the functioning of society, and lastly, identifying possible alternatives in this particular use.[88] Functions include "end-use", "service" and "chemical" functions, which consider performance of chemicals and the necessity of end-use and service functions.[89]

This theoretical framework can be demonstrated in practice through different examples. Substances considered as non-essential, such as ski waxes in order to ski faster, are nice to have, but society can function without them, meaning that they could be phased out as non-essential substances.[90] Substitutable substances have alternatives.[91] An example of these

80 Garnett and Van Calster (n 35), 160.
81 Cousins et al (n 11), 1804.
82 Garnett and Van Calster (n 35), 168.
83 Ibid.
84 Cousins et al. (n 11), 1804-5.
85 Ibid 1804.
86 Ibid.
87 Ibid 1805.
88 Ian T. Cousins et al. 'Finding Essentiality Feasible: Common Questions and Misinterpretations Concerning the "Essential Use" Concept' [2021] 23 Environmental Science Processes Impacts, 1079, 1081.
89 Ian Cousins et al. (n 89), 1081.
90 Cousins et al. (n 89), 167; See also Cousins et al. (n 11), 1805, where category 1 substance examples include non-stick cooking utensils.
91 Ibid; See also Cousins et al. 2019 (n 11), p.1805, where a substitutable substance is highlighted to have necessary technical function and performance.

substances are PFAS chemicals in fire-fighting foams, as fluorine-free foams have been created and are replacing aqueous film-forming foams.[92] The last category, essential substances, are included in, for example, medical devices that cannot be phased out or banned, and as of yet do not have alternatives.[93] For example, essential uses of PFAS substances in surgical gowns provide repellency against liquids, viruses, bacteria and aid in keeping the textile breathable.[94] The PFAS substances are essential, as the chemical and service functions provide liquid repellency, while the end-use is to protect hospital workers.[95] This theoretical concept should be further considered in terms of the current REACH regulation process, its legal feasibility in practice, as well as how the EU views the concept.

4. ESSENTIAL USE IN PRACTICE: REACH AND PFAS

Recently, a final report was published to support the European Commission in developing the essential use concept, in which the Commission has committed to the Chemicals Strategy for Sustainability Towards a Toxic-Free Environment (CSS, 2020).[96] CSS plans to define the concept in order to allow only harmful chemicals that are necessary for health, safety or the "functioning of society", if there are no other substitutes that can be accepted in terms of the environment and health.[97] This suggests a political will, at least on paper, to develop the current EU legislation to specifically phase out chemicals that are not socio-economically necessary for society.[98] This political will is linked to various EU policy strategies (the European Green Deal, Chemicals Strategy for Sustainability, the Zero Pollution Action Plan and the Circular Economy Action Plan) aiming for a "toxic-free society".[99] The concept could simplify REACH and make the process of registration and authorization easier, quicker and safer for the environment and the health of society.

The final report attempts to aid the European Commission in developing a "horizontal essential use concept" that can be applied within various legislation, including amending the current REACH regulation.[100] The final report summarizes key findings made in a research using workshops, surveys, interviews, and public consultations on how the essential use concept

92 Ibid 1081.
93 Cousins et al. (n 89) 1081.; See also Cousins et al. 2019 (n 11), 1805, where it is mentioned that essential use substances are to be eventually phased out through research and development or engineering to make alternatives available.
94 Ibid.
95 Ibid.
96 See European Commission Directorate-General for Environment 2023 (n 9).
97 Bougas et al (n 80) 7.
98 European Commission Directorate-General for Environment 2023 (n 9), 4.
99 Bougas et al (n 80), 7.
100 European Commission Directorate-General for Environment 2023 (n 9), 4.

should be applied within the existing EU regulation landscape.[101] The paper relies on the Montreal Protocol and refers to Cousins et al. which shows the importance of the academic research published on the essential use concept.[102] Considerations are made in identifying essentiality, as placing a wide net in what is considered "essential" would allow many harmful chemicals to be continuously used within society, while limiting chemicals in the "non-essential sectors" might target chemicals excessively within the current market.[103] This uncertainty is key to keep in mind in terms of different academic opinions on creating essential use within REACH. All amendments to the regulation must also be legally feasible in the EU. The fourth section of this paper uses the findings of the report to consider how essential use may be applied within REACH in practice in the regulation of PFAS, and other SVHC, chemicals.

4.1 Different Options of Essential Use Within REACH

The Final Report considers different models of regulatory reforms in terms of the essential use concept within REACH. These options include adding a form of optional guidance (non-legally binding) of essentiality to the current regulation within authorization and restriction (sub-option A), reforming authorization and restriction using an implementing Act based on Article 291 on TFEU and 132 of REACH (sub-option B), slightly modifying the current authorization and restriction phases (adequate control and socio-economic paths) and adding an essential use concept to define analysis in both routes (sub-option C), or replacing the adequate control and socio-economic analysis paths in authorization and modifying the current structure of analysis using the essential use concept (sub-option D).[104] Sub-option D is most extensive, and includes replacing the current system of authorization in REACH using the concept.[105] The report weighs in the positive effects of making the current regulation simpler and the negative economic impact it may have on industry.[106] The report concludes that the option D is legally feasible, predictable, coherent, and the best way to protect health and the environment.[107] The change would result in the least amount of costs, and it would have the most benefit in terms of the "administrative burden" for industry and the EU.[108] Therefore, the analysis done within the report

101 Ibid 5.
102 See pages 18, 35, 50 and 56 of the Final Report by the European Commission Directorate-General for Environment 2023 (n 9).
103 European Commission Directorate-General for Environment 2023 (n 9), 6.; See p. 7 for an overview of the concept within horizontal use.
104 Ibid 103.
105 Ibid 9.
106 Ibid.
107 Ibid 170.
108 Ibid.

considers that the current REACH regulation should be updated with legal changes by adding a new regulatory essential use framework to the authorization process of REACH. This outcome should be considered in terms of different academic opinions on the feasibility of this reform.

Figuière et al. published an article on how the essential use concept may be specifically used within the authorization process of REACH in an efficient manner. Specifically, Figuière et al. considers the information requirements that an applicant submits to apply for authorization of a SVHC chemical on the internal market.[109] The applicant must submit a Chemical Safety Report on the substance's risks, an analysis of substitutes and how substitutes may be used in the future, while socio-economic analysis is optional.[110] The current data submitted can be used, in Figuière et al. opinion, in a new framework of essentiality of using the substance, especially if socio-economic analysis proves that the benefits in using the chemical do outweigh its risks.[111] However, the authors claim that the definitions of socio-economic benefits are not properly defined, therefore, specific terms must be clarified for an essential use analysis.[112] Figuière et al. come to the conclusion that there are "no legal barriers" to implement essential use in the authorization process of REACH.[113] However, REACH must have clear definitions of "socio-economic benefits" and risks.[114] This is also considered by Cousins et al., who emphasize that the conceptual framework must have a clear criteria and pre-defined process.[115] Figuière et al. view of how to implement essential use within the current regulatory framework does not propose wider changes to the current system of analysis. The paper can be compared to Monfort's article, which considered essential use from a wider and a more legal standpoint.

Montfort considers that the concept of proportionality is key in adopting any changes to the current regulation. The Union is founded on key principles. Proportionality signifies that EU measures must not go above what is "appropriate and necessary" in achieving the designed legal objectives.[116] Therefore, all legal measures must also consider whether the EU has the competence to make legal decisions in the field in question, and whether these changes are acceptable in terms of the founding principles of EU law. Montfort considers that an overarching essential use criteria would go against the principle of proportionality. I agree with this statement, as outright bans based on essentiality would be disproportionate. Montfort proposes the use of a fast-track system, meaning that once the EU would deem a product to fit certain essential

109 Figuière et al. (n 37) 5.
110 Ibid 8.
111 Ibid 8-9.
112 Ibid 9.
113 Ibid.
114 Ibid 10.
115 Cousins et al. (n 11) 1806.
116 Montfort (n 74) 9.

use standards, the EU would make fast-tracked decisions on these chemicals.[117] The EU would define a set of products and goods that are considered to be essential, and possibly non-essential by end-use analysis, and industry would need to prove that they meet the certain set of standards for a fast-tracked decision.[118] The rest would go through standard procedure added with a socio-economic analysis of essentiality and impact.[119] The system would work vice versa in that if a product would be deemed non-essential, they could be fast-tracked to be banned unless strict conditions are met.[120] However, it must be considered whether this idea would actually make the process of REACH any faster. Just because some chemicals would be put onto a fast-tracked list does not mean that ECHA would be able to analyze these chemicals any faster within the current system of analysis added with a mandatory socio-economic analysis. Therefore, I believe Montfort's idea could be developed with sub-option D in the Final Report supporting the Commission.

4.2 Analysis of the Different Options of Essential Use

There are multiple options in how to implement essential use within REACH, meaning that the EU has a wide array of choices in how to change the current regulation to become more efficient. Montfort's fast-track process could be combined with a more refined system of restriction and authorization in terms of essential use. As already mentioned, authorization and registration processes differ within the REACH analysis processes. The modifications that have been considered in terms of essential use focus on changing the current authorization processes. However, the entire REACH process could be modified with an overarching horizontal essential use regulatory processes at an earlier phase of registration, going even further than what was proposed in sub-option D of the Final Report. In addition, Montfort's fast-track system could be beneficial to outline the process in order to make quicker decisions on specific essential chemicals. For example, if certain SVHC PFAS chemicals would be included in essential medicinal devices, ECHA would fast-track decision-making using a clearly defined essential use criteria (essential, substitutable, or non-essential) to allow the use of the chemicals within the EU, given that no substitutes would be available. On the other hand, unsafe chemicals included in the coating of non-essential products such as ski waxes would be fast-tracked to be phased out. These changes must be made proportionally, and each term of the process must be defined clearly.

117 Montfort (n 74) 11.
118 Ibid.
119 Ibid 12.
120 Ibid.

Proportionality and clearly defined terms are key considerations to keep in mind while legally changing regulation. Clearly defined terms avoid creating disproportionate bans and may alleviate industry lobbying. Therefore, using terms defined by Cousins et al. could be a starting point with further definitions of socio-economic benefits, as industry lobbying has already created delays in the process of revising REACH. In July, reports indicated that planned updates to REACH in banning hazardous substances have been delayed due to lobbying by the chemical industry.[121] Revisions of REACH are expected by the end of the year, but there are concerns of how ambitious these may be, as industry actors are anxious of the subjectivity of essentiality, especially in terms of cultural significance.[122] In addition, there are reports of a complete reversal in revising REACH in favor of reducing industry administrative burden. Decisions should be made before the May 2024 European Parliament elections, as they may stall the current process of revising REACH.[123] Therefore, essential use must be clearly defined in modifying REACH to show the chemical industry that there would not be disproportionate bans of chemicals, but swifter decision-making by ECHA in grouping substances based on essentiality of use. In addition, industry should be made mindful that finding new substitutes to harmful chemicals in the end means more innovation, therefore, better, and safer products.[124] It is much more favorable for the chemical industry to use innovative and less harmful chemicals to also lessen the costs of regulatory actions.

5. CONCLUSION

It is clear that the essential use concept can develop the REACH regulation, especially in terms of regulating SVHC chemicals. Specifically, certain PFAS chemicals as SVHC chemicals have been grouped by academics through the essential use lens in order to regulate them as a wider group. Essential use as a theoretical concept is multilayered and flexible in that it has many ways in which it can develop REACH as a regulation. The paper suggests that the theory should be modified in terms of research to form a coherent regulatory structure to be implemented within

121 Arthur Nelsen, "EU to Drop Ban of Hazardous Chemicals After Industry Pressure" (The Guardian, 11.07.2023) <https://www.theguardian.com/environment/2023/jul/11/eu-to-drop-ban-of-hazardous-chemicals-after-industry-pressure> accessed 09.09.2023.

122 Kira Taylor, "What is Essential? The Question Overshadowing Europe's Chemical Law Reform" (Euractiv, 14.07.2023) <https://www.euractiv.com/section/chemicals/news/what-is-essential-the-question-overshadowing-europes-chemical-law-reform/> accessed 09.09.2023.

123 Charlotte Elton, "'Profit More Important than Europeans': EU Blasted for Proposed Delay in Cleaning Up Toxic Chemicals" (Euronews, 17.10.2022) <https://www.euronews.com/green/2022/10/17/profit-more-important-than-europeans-eu-blasted-for-proposed-delay-in-cleaning-up-toxic-ch> accessed 09.09.2023.

124 Cousins et al. (n 89), 1083.

the current REACH processes of analyzing SVHC chemicals. Updating the current regulation in terms of essentiality of substances would push for a more efficient regulatory process. There is a growing political will within the EU to phase out toxic chemicals, however, industry lobbying has set back reforms. The chemical industry should be presented with an updated REACH structure to help clear administrative confusion, especially since the current political climate shows that reforms are being pushed back through lobbying. Innovation to create a toxic-free society comes from efficient reforms to regulation. This innovation also requires good communication between industry and regulators.

The findings of the paper can be further considered in terms of other chemical groups under the SVHC list. Further research should be made to be able to create a horizontal model of essential use to be applied across other regulations and directives. Also, a clear step-by-step process of implementation of the concept, as well as instructions on how it may be applied in practice by regulators would aid in understanding the practical side of the theoretical framework.