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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"),

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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

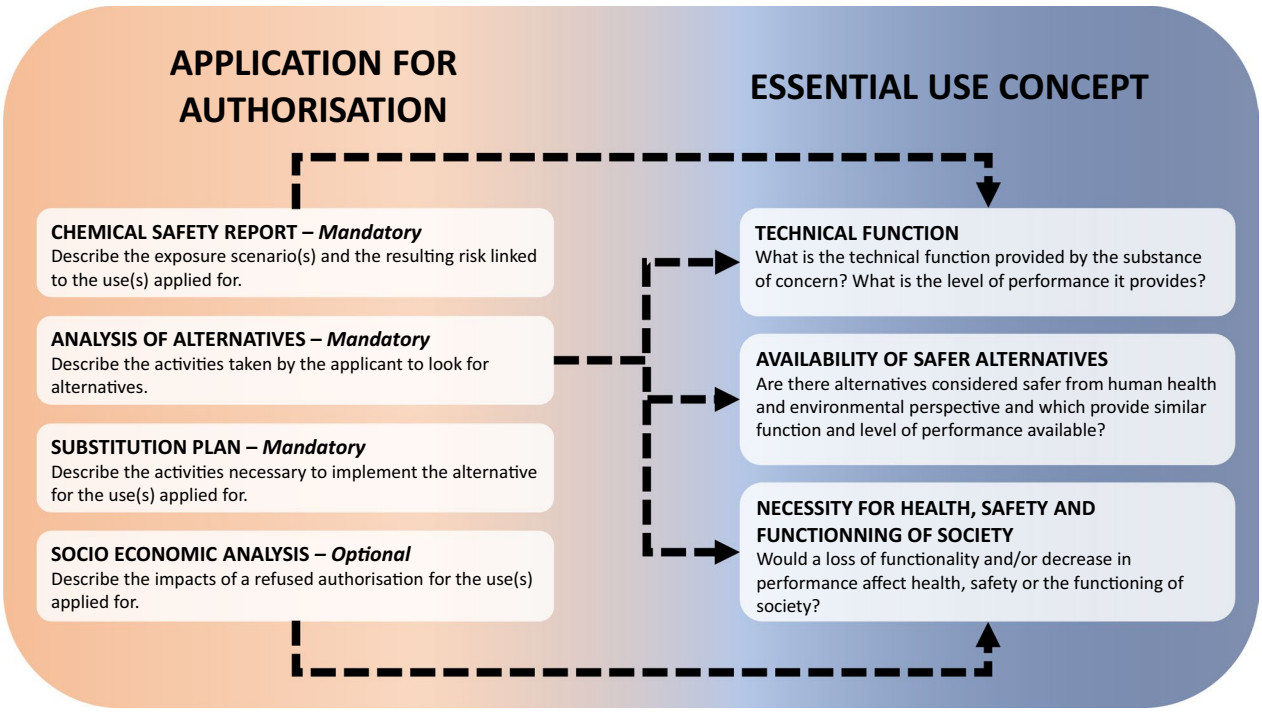

Fig. 1 Schematic showing how the information required in an application for authorisation can be used in an essentiality assessment of the use applied for

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.

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The authors declare that they have no competing interests.

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