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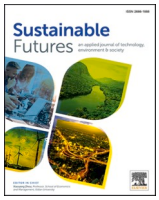

Connecting the dots: Integrating the 'essential-use' concept in the chemical management framework of a product system

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ABSTRACT

This study explores the essential-use concept within a broader chemical management framework for a product system, aimed at phasing out non-essential chemical uses. This concept mandates the elimination of all non-essential applications of chemicals of concern unless their use is crucial for health, safety, or societal functioning, and no technically and economically viable, non-regrettable alternatives available. This study traces the evolution of the essential-use concept and its current implications in chemical management, aiming to understand its applicability. By translating technical terminologies into a more understandable language, this study seeks to bridge the knowledge gap between specialists and the public, enhancing grassroots-level acceptance of the concept in product system chemical evaluation. It addresses the subjective nature of defining the essential-use concept and examining the inherent contradictions society faces in aligning it with safe uses to protect both human health and the environment. It also introduces complementary concepts to essential-use in chemical management, supporting the discussion with the development of a holistic chemical management framework for a product system. This framework incorporates the essential-use application in a way that makes the concept more easily comprehensible. The developed framework provides a systematic process for managing chemicals within a product system, simplifying chemical management at the product level until the product is deemed safe for use. This study also emphasizes the need for further research on how the essential-use concept can effectively guide the phase-out of harmful substances through grouping and prioritization, considering various perspectives and uncertainties. This is crucial for informed decision-making and promoting sustainable chemical use by eliminating non-essential chemical uses within product systems.

1. Introduction

The expansion of the global chemical landscape is evident, as highlighted by the Chemical Abstracts Service (CAS), which has cataloged over 275 million registered substances by 2024 [1]. While chemicals offer numerous benefits, their release throughout the product lifecycle can lead to adverse impacts on human health and the environment, as shown by previous research publications [2–5]. The impacts of chemical emissions, recognized as a critical planetary boundary, are not fully understood, posing risks to environmental sustainability and intensifying other global challenges such as climate change and biosphere integrity [6–8]. A notable study by Wang et al. [5] on national and regional chemical inventories showed the scale of chemical use, revealing the registration of over 350,000 chemicals and chemical mixtures for production and use. Alarmingly, a significant number of these chemicals lack public visibility, with over 50,000 being confidential and about 70,000 poorly described, thus concealing their potential effects [5]. The limited transparency in chemical identities, combined with inadequate disclosure and assessment of their environmental and health impacts, underscores the significant challenges in managing chemical pollution and protecting human and environmental health [9,10].

However, registration and identification of chemicals do not necessarily indicate their use. It is estimated that 40,000 to 60,000 industrial chemicals are in global commerce, based on data from the European Union (EU), United States (US), Canada, Japan, and China with approximately 6000 of these chemicals account for >99 % of the total volume of industrial chemicals used worldwide [11,12]. Beyond industrial applications, a wide range of chemicals is found in consumer products, including cosmetics, cleaners, plastics, electronics, furniture, and more. The United States Environmental Protection Agency (U.S. EPA) Chemical and Products Database (CPDat) lists over 75,000 chemicals and >15,000 consumer products [13]. The number of chemicals estimated to be used in commerce, released into the

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environment, or exposed to humans is considerably smaller. This narrows the scope of chemical concerns to those that are actually in use and lead to exposure, potentially resulting in toxicity.

Chemical regulatory frameworks at regional, national, and international levels have historically been foundational in managing chemicals through screening, prioritizing, and assessing [14–17]. However, with new chemicals continuously entering the market, these systems, relying on conventional hazard and risk assessment methods, are struggling to regulate the ever-growing number of chemicals effectively [18]. These methods are systematic processes used to identify and evaluate the potential risks associated with chemical substances and typically include hazard identification, dose-response assessment, exposure assessment, risk characterization, risk management, and risk communication [19, 20]. Current regulatory approaches based on risk assessments are inadequate for handling the vast array of chemicals in commerce, with some jurisdictions taking over ten years to complete risk assessments for existing chemicals [21,22]. The European Commission and European Chemicals Agency (ECHA) acknowledge the effectiveness of the EU authorization process in substituting Substances of Very High Concern (SVHCs) but face significant implementation challenges [23–26]. For instance, of the 26,147 substances registered under REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals), only 2300 have been evaluated since 2009, and by September 2022, only 455 SVHCs were identified, with fewer subjected to authorization [27–29]. This regulatory gap provides little incentive for companies to disclose and access chemicals in their products [9]. Moreover, restricted chemicals are often replaced with similar, potentially unsafe substitutes due to insufficient evidence based regulatory requirements [30–32]. Given these challenges, innovative chemical management strategies are urgently needed to minimize the use and exposure to hazardous chemicals in products.

There is an increasing shift towards methodologies like Life Cycle Assessment (LCA), Chemical Alternatives Assessment (CAA), green chemistry, and the concept of planetary boundaries to mitigate chemical impacts in product systems. To further enhance chemical management, the “essential-use” approach could be effectively integrated into current regulatory systems [25]. This approach could revolutionize chemical management in a product system by enabling more rapid and efficient assessment of chemicals of concern (CoC), phasing out non-essential uses, and fostering market innovation towards safer alternatives [9, 33]. The concept mandates the elimination of all non-essential applications of CoC unless their use is crucial for health, safety, or societal functioning, and there are no technically and economically viable, non-regrettable alternatives available. The integration of grouping and prioritization strategies in chemical management increases its effectiveness. Traditional risk-based approaches focus on individual chemical assessments but are increasingly shifting towards chemical grouping to optimize resources [33,34]. This shift is particularly relevant for avoiding the use of chemicals with the potential to cause irreversible harm [35]. Grouping is especially effective when toxicity data is available for some but not for all substances within a group. By employing precautionary principle, chemically similar substances can be treated as a group. The precautionary principle in environmental science advocates for preventive action in environmental decision-making for reducing potential harm when there is significant scientific uncertainty about chemical risks, alongside reasonable grounds for concern [36,37]. This principle emphasizes caution regarding environmental and public health concerns. For instance, many substances group includingper- and polyfluoroalkyl substances (PFAS) are known to be ’persistent,’ ’mobile, ’ and ’toxic’ [38,39]. With thousands of PFAS currently in use, case-by-case risk evaluation becomes unfeasible, prompting support for precautionary approach with a group-wide ban on PFAS in different uses [39–42]. Grouping often results in more effective chemical management strategies. The essential-use concept can be used in collaboration with the chemical grouping approach.

This study explores the essential-use concept in the context of chemical management framework of a product system, for phasing out non-essential chemical uses. It provides an overview of the development and current landscape of the essential-use concept in chemical management. The objective is to discuss this concept, making it more accessible and understandable to a wider audience, while connecting it to other relevant concepts in chemical management. By translating complex technical jargon into understandable language, this study aims to bridge the communication gap between experts and the public for its grassroot level acceptability in product system chemical evaluation. This study also develops a systematic and holistic chemical management framework for a product system, integrating the essential-use application along with other complementary chemical management strategies. This practical framework can support informed decision-making and promote safe and sustainable chemical use in products by reducing non-essential chemical uses.

2. Methods

2.1. Essential-use concept literature review methodology

This study conducted a small literature review with a systematic approach following a structured procedure: identification, screening, eligibility, and analysis [43]. The literature search was initiated using the Scopus database [44] with a search string: (“essential* use*” OR "essential*use*") AND “chemical*”. This query was aimed at retrieving research publications from Scopus, focusing on titles, abstracts, and keywords. The scope of the search included literature published up until the end of January 2024, yielding a total of 100 results. The objective was not to conduct an exhaustive review but rather to obtain a representative sample of publications that would provide a systematic overview of the essential-use concept in the context of chemical use.

During the screening phase, the abstracts of these publications were reviewed. Those found to be irrelevant to the study’s focus were excluded, resulting in the elimination of 71 articles. This exclusion primarily pertained to publications that discussed the essential-use concept outside domain of chemical application, which fell beyond the purview of the study. The remaining 29 articles as given in the supplementary information, comprising 13 research papers, 3 conference papers, 1 editorial, 2 notes, and 10 review articles, were then read in detail. This study analyzed each of these publications to gain a comprehensive understanding of how the essential-use concept is applied in the chemical landscape within the existing literature. The literature review is used to find complementary concepts associated with essential use concept in the broader chemical management framework.

2.2. Developing a chemical management framework for a product system

This study introduces a streamlined and holistic chemical management framework of a product system that encapsulates the essential-use concept and interlinks various chemical management strategies, such as CoC, safe limits, alternatives assessment, and functional substitutions. The aim is to bridge the gaps between different concepts thereby enabling practical application of all the concepts in a holistic way in real-world scenarios involving chemicals in a product system.

The genesis of this framework is rooted in the ongoing debate over the application of "essential-use"—a debate that explores whether the term refers to the essentiality of a product, the function of a chemical within a product, or the fundamental importance of a chemical’s function to the user’s quality of life. While this concept is well understood in academic circles, it is not clear to the general public, who are often viewed as the driving force behind political decisions to restrict the use of toxic chemicals in product systems. By breaking down these concepts into more accessible terms, the framework seeks to clarify common misunderstandings and align technical definitions with public perception. Ultimately, this aims to foster a more informed dialogue on

chemical essentiality within a product system, facilitating its effective implementation in a holistic chemical management framework that enhances both environmental safety and human well-being.

3. Theory

3.1. Defining essential-use and its associated complementary concepts in chemical management

This section explores the concept of essential use and its associated terminology, as informed by the literature review. The interplay between the essential-use concept and its complementary principles is illustrated in Fig. 1. It is important to note that the concept of essential use does not operate in isolation within chemical management of a product system. Instead, it is a part of the holistic chemical management system with other complementary strategies. These include the definition of CoC, the establishment of safe limits for chemicals, the practice of functional substitution, and the implementation of alternatives assessment. Additionally, strategies such as chemical grouping, green chemistry principles, risk assessment methodologies, and considerations of chemical circularity and chemical exposure are helpful in the effective application of essential-use concept. This multifaceted approach ensures holistic and effective management of chemicals, emphasizing safety, sustainability, and the reduction of adverse environmental and health impacts.

3.1.1. Essential-use concept

The essential-use concept, as discussed in the context of chemical management, was initially introduced to regulate the production and usage of ozone-depleting substances in 1977 [34], further crystallized in the 1987 Montreal Protocol Decision IV/25 [45]. This concept grants exemptions to the use of specific chemicals in specific products that were deemed essential, characterized by their necessity for health, safety, or societal functioning, and the absence of technically and economically viable, non-regrettable alternatives [46]. Notable examples of essential uses span across medical applications, laboratory and analytical purposes, aerospace, firefighting, etc., explicitly excluding products of luxury, convenience, or decorative nature [34,47].

To facilitate the phasing out of PFAS, Cousins et al. [46] proposed a classification of essentiality into three categories: (1) non-essential uses, (2) essential but safely substitutable uses, and (3) essential and non-substitutable uses. For category 1, labeled as "non-essential" uses, it is recommended a phase-out through bans or restrictions. For category 2, "substitutable" uses, the strategy involves enhancing the visibility, availability, and affordability of non-regrettable alternatives to encourage market adoption. Lastly, for category 3, "essential" uses, the focus shifts towards fostering the discovery of non-regrettable functional alternatives through innovative research and development. This includes providing robust market incentives, securing funding, and supporting start-ups dedicated to creating and commercializing new, safer alternatives. This tiered approach aims to streamline the transition towards safer chemical use by aligning regulatory measures, market dynamics, and innovative efforts. Only those uses categorized as essential and non-substitutable are recommended for authorization under the essential-use framework [48]. Another condition for essential use is the mandate that all economically viable measures to minimize emissions and to control exposure of CoC must be implemented [25,45,49]. Additionally, approval is granted on a conditional, time-limited basis, contingent upon meeting criteria of essentiality complemented by a substitution plan for developing safer alternatives, thus incentivizing market innovation and voluntary actions [9,46]. This approach is designed to offer a transition period for adapting to changes in essential uses [35]. Beyond the Montreal Protocol, the essential-use concept has been refer implicitly into other regulatory frameworks and chemical strategies, such as the EU REACH Regulation, the Stockholm Convention, and the EU Biocidal Products Regulation, as well as the EU Chemicals Strategy for Sustainability, underscoring its significance in chemical management efforts [15,16,33,50–52].

In the context of essential-use, the term "use" refers to the function provided by the chemical within a product system, including chemicals application during manufacturing processes, regardless of its presence in the final product [9]. The essential-use concept is not about the essentiality of a chemical or a product, but it is about the essentiality of the function provided by a CoC, for example, PFAS, in a product system to its user that led to toxic exposure [34]. The ECHA advises manufacturers to engage with downstream users for an understanding of the specific function of SVHCs and to explore potential alternatives by consulting stakeholders beyond their immediate supply chain [53]. Figuière et al. [25] emphasize that identifying the technical function of the CoC is the preliminary step in assessing essential use, which can be facilitated by the use descriptor system under REACH. This system includes seven descriptors: Life-cycle stages, Sectors of use, Chemical product categories, Process categories, Environmental releases categories, Article categories, and Technical function [54].

The challenge lies in the "grey zones" or areas of uncertainty regarding the objectively defining the essential-use criteria and the identification of decision-making authority when alternatives are not available. According to van Dijk et al. [48], Cousins et al. [46] and Bălan et al. [9], the absence of universally accepted criteria for defining essential-use necessitates a case-by-case, decentralized approach with qualitative assessment by a range of decision-makers, from business owners to regulatory bodies. Bălan et al. [9] propose forming an expert advisory panel, with diverse stakeholder participation under a strict no conflict-of-interest policy, placing the responsibility on the producer to justify the essentiality of CoC use.

3.1.2. Functional substitution

The concept of substitution within essential-use refer to functional

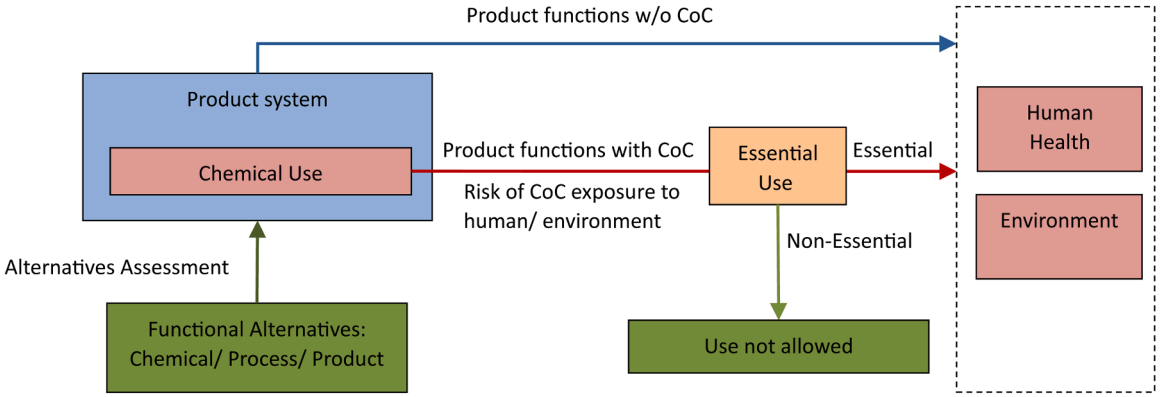

Fig. 1. Conceptual model of chemical risk and its associated concepts.

substitution [33], as recognized in the United Nations Global Chemicals Outlook II and the ECHA Substitution Strategy [55,56]. It involves identifying safer and effective alternatives for a CoC function, whether through chemical, product/process design, or service alternatives, to meet the functional use requirements [33]. Tickner et al. [57] describe three levels of substitution: chemical function, end-use function, and function as a service. Roy et al. [33] further clarify that substitution does not necessarily entail a complete replacement but rather achieving a sufficient level of function, opening doors to safer, albeit potentially less effective, solutions. Cousins et al. [34] advocate for setting technical performance standards to ensure that alternatives adequately perform the intended function as fit-for-purpose performance.

3.1.3. Alternatives assessment

Alternatives assessment stands as a crucial component of the chemical management framework, serving as a process for evaluating and selecting safer options to avoid regrettable substitutions. This approach is recognized for its comprehensive evaluation of hazards and the potential trade-offs, advocating for a transition towards safer chemical or non-chemical alternatives [58,59]. Defined as a science-driven, iterative, and solutions-oriented method, to facilitate the substitution process by systematically identifying, comparing, and selecting safer alternatives [60–64]. The methodology includes several stages: defining the scope, formulating the problem, identifying potential alternatives, and conducting thorough assessments across various parameters including physicochemical properties, hazards, exposure levels, technical feasibility, economic viability, environmental impacts, and social considerations. The process culminates in a decision-making phase that integrates insights from the entire life cycle of the alternatives [61,65]. Figuière et al. [25] highlight the value of multicriteria analysis as a key instrument in balancing both qualitative and quantitative impacts during the assessment of alternatives for essential-use, ensuring a holistic and informed selection process.

3.1.4. Chemical of concern (CoC)

The concept of "CoC" is pivotal within the essential-use framework; however, its definition and the authority to designate such chemicals can vary. What is considered a CoC according to one authority may not be classified as such by another authority within the same region or in a different region. This inconsistency is why chemical companies might stop selling a chemical due to a ban in one location but continue to sell it in another location [66]. The EU Chemicals Strategy for Sustainability describes CoC as substances detrimental to human health or the environment, and those that obstruct the recycling process for creating safe, high-quality secondary materials [15]. The criteria for identifying these chemicals can vary widely, encompassing a broad spectrum of hazard traits such as toxicity to humans and ecosystems, persistence, mobility, and (bio)accumulation. Additionally, identification can draw on various regulatory and non-regulatory lists, including chemicals regulated under the Toxic Substances Control Act, California's Safer Consumer Products Regulations, the REACH SVHCs, list of carcinogens from the International Agency for Research on Cancer (IARC), manufacturers "Red List" of chemicals, among others. Furthermore, chemicals can also be classified CoC based on grouping on the basis of shared physicochemical and toxicity characteristics, production volumes, or the diversity of their uses [4,9,61]. In essence, the determination of CoC may consider one or more of the following factors including hazard traits, specific lists from regulatory frameworks, the potential for environmental and health impacts, and considerations of transformation products, accumulation and mobility, circularity concerns, chemical production, and application diversity. It underlines the diversity in defining CoC, emphasizing the multifaceted strategy that addresses the broad range of potential risks associated with chemical usage and its implications for sustainability and circular economy initiative.

3.1.5. Chemical grouping

The prevailing approach to chemicals management, focusing on individual chemical assessments, is increasingly seen as untenable due to the sheer volume of chemicals in use and the significant gaps in available data about them [34]. Recognizing these challenges, the application of essential-use concept can shift from traditional substance-by-substance approach to a more efficient, group-based strategy. This transition aligns with the Chemicals Strategy for Sustainability, which explicitly calls in Section 2.3.1 for a departure from substance-by-substance regulation in favor of group-based regulation [15]. Cousins et al. [46] suggest that the essential-use concept can be effectively combined with chemical grouping, especially for assessing classes of CoC, such as PFAS. This involves grouping chemicals with similar physicochemical, health, or environmental characteristics to streamline the assessment of their essentiality and manage them more cohesively as a class [9]. One strategy can be the subdivision of chemical groups by use categories or functional characteristics, facilitating targeted decisions on the elimination or substitution of specific chemical uses. Another approach can be chemical grouping in combination with prioritization strategies for a multi-dimensional analysis, determining priority based on factors like green chemistry principles, specific chemical functions, or the chemical use categories, among others. Moreover, grounding grouping strategies in the precautionary principle, particularly in cases like the PFAS restriction proposal, underscores the importance of erring on the side of caution to prevent irreversible harm by treating toxic chemicals as one group [35]. This method not only ensures a more systematic and holistic regulatory process but also minimizes the risk of regrettable substitutions by avoiding replacements within a problematic class of chemicals [9].

In recent years, New Approach Methodologies (NAMs) have represented a significant advancement in screening extensive chemical libraries for biological activities [67,68]. Utilizing high-throughput screening (HTS) technologies, NAMs rapidly evaluate numerous chemicals, efficiently generating data on potential toxicological effects and reducing reliance on extensive animal testing [69–71]. They thus enhance grouping-based approaches by identifying groups of chemicals with similar properties or effects that are not evident through QSAR alone [72]. This capability can be used for characterizing substance similarity to support the grouping of chemicals [73].

3.1.6. Chemical substitution plan

The granting of time-limited approval for essential uses mandates the development of a substitution plan aimed at creating safer alternatives [9,46]. A pivotal strategy in this process is the application of Green Chemistry, which focuses on the design of safer chemicals by adhering to the 12 Principles of Green Chemistry. These principles serve as a comprehensive framework for making molecular design decisions that minimize environmental and health impacts [74]. The California Safer Consumer Products (SCP) program, established under the 2008 Green Chemistry Law, underscores this approach by seeking to diminish the reliance on hazardous substances and fostering the discovery of safer chemical alternatives in consumer products [75]. Malloy et al. [76] and Malloy et al. [77] emphasize how green chemistry principles empower manufacturers to proactively seek and incorporate greener alternatives early in the product development cycle, thereby aligning product innovation with environmental sustainability and public health objective.

3.1.7. Risk assessment

Roy et al. [33] argue that for the phase-out of "most harmful substances" relying solely on risk assessment may not be adequate due to the potential for irreversible impacts on health or ecosystems at different stages of a product system from production to disposal. In the traditional "risk-based" approach to chemical regulation, decisions are based on the available scientific evidence regarding the characterization of potential adverse effects from chemical exposures and whether a substance is

harmful enough to warrant restriction [78]. Risk assessment of chemicals is a systematic process used to evaluate the potential risks to human health and the environment from exposure to chemicals [19,20]. It is a critical component in environmental health and safety management, generally involving four key steps [79–81]. The process begins with Hazard Identification, which determines the adverse effects that can be caused by exposure to the chemical. This is followed by Dose-Response Assessment (hazard characterization) to define safe exposure levels. Next is Exposure Assessment, which estimates predicted human or ecological exposures to the chemical. The process concludes with Risk Characterization, which describes the nature and magnitude of health risks to humans and the ecosystem from chemical exposures. The risk assessment process is underpinned by scientific research and is used by various agencies worldwide, such as the U.S. EPA, the ECHA, and other national and international bodies, to ensure that chemicals are used safely and sustainably, minimizing adverse effects on health and the environment [16,82–86].

3.1.8. Chemical circularity

Wang and Hellweg [87] include chemical circularity assessment in the essential-use concept, emphasizing on two key considerations: the circularity of the chemical itself and its influence on the circularity of other chemicals, materials, and products, categorizing them as enablers, neutral, or inhibitors of circularity. This approach suggests that chemical use can be justified in situations where its own circularity is compromised or if it acts as an inhibitor to the circularity of other substances only if it is classified as essential. This perspective is further supported by the European Commission, which incorporates a circularity dimension into the essential-use criterion, asserting that the use of "the most harmful chemicals" should be deemed essential only if it contributes to "achieving a climate-neutral and circular economy" [25,88]. This integration underlines the need to balance chemical use with overarching environmental goals, reinforcing the essential-use concept with a broader, sustainability-oriented framework that considers the lifecycle and circularity impacts of chemicals.

4. Results and discussion

4.1. Proposed essential-use based holistic chemical management framework

To illustrate the concept of essential-use as it applies to chemical management, it is important to grasp a few key elements in the product system scoping. It includes the chemical itself, the product that contains the chemical, the usage of the product, and the specific function that the chemical provides within the product. Firstly, the CoC in question forms the foundation of chemical management. It is the chemical function whose essentiality or non-essentiality is being evaluated. Then, the focus shifts to the product that incorporates this chemical. Understanding the nature of the product is crucial as it provides context for the chemical's application, its users and potential exposure. The third aspect involves the usage of the product, which essentially brings into play the end-user and how they interact with the product. This is a critical component as it directly relates to how and why the chemical is being used in product function, offering insights into its essentiality. The fourth and final element is the function that the chemical performs within the product. This includes understanding the role that the chemical provides, which is key to assessing its importance in the product's application. Beyond these core elements, the scope extends to the availability of functional alternatives to the chemical function and alternatives safe limits. Safe limits are evaluated in both absolute and relative terms. Absolute safety in the context of chemicals is defined by their documented potential to be a chemical of concern, warranting the establishment of safe limits that consider both current and future uses of the chemical. This concept aims to preemptively address any risks associated with a chemical's usage over time. On the other hand, relative safety pertains to how a chemical aligns with existing societal hazard standards for various substances. The establishment of a safe limit for a chemical indicates that the chemical possesses properties that could be hazardous. Both concepts are crucial in assessing and managing the risks associated with chemical usage, ensuring that safety considerations are balanced against practical applications.

Furthermore, the study acknowledges the philosophical and subjective aspects surrounding the concept of chemical function essentiality. This includes the determination of whether chemical function is vital for health and safety or critical to the functioning of society, and how these perceptions can vary among different users and individuals. This is further divided into two categories: chemicals essential for the survivability of society in absolute terms, indicating that their absence would result in direct physical or mental harm to humans, and chemicals essential for societal functioning in relative terms, referring to those whose absence would lead to a lower quality of life relative to current societal benchmarks. This delineates the complexities involved in determining the essentiality of chemical use, highlighting its multifaceted nature and the need for a comprehensive understanding in various contexts.

To understand the proposed framework, it is important to recognize that it involves the use of a chemical within a product system. This chemical could either be the sole component of a product or part of the supply chain. The first phase of the proposed framework is the system scoping phase to understand the products system and the chemical use in the product system. It starts by identifying whether the product system under consideration contains any chemicals. If there is no chemical included in the product system, the assessment concludes with the product being deemed acceptable to use. Otherwise, the next step is to determine if the chemical in the product system is safe or not. This is based on determining whether the chemical in the product system is a 'chemical of concern' (CoC), both in absolute and relative terms. In absolute terms it means it has already been recognized as 'CoC,' and has a safe limit set by governmental or legal authorities. In relative terms, this means assessing if the chemical may have a safe limit set in the foreseeable future, considering its toxicity or use quantities to consider it as a potential CoC. Overconsumption of any chemical can be harmful, but the focus is on involuntary exposure that an individual cannot control in their daily life. If any responsible organization, whether governmental or non-governmental, identifies a chemical as a potential concern it is then unsafe in relative terms. Following this assessment, a chemical can be classified as safe, a potential CoC, or an identified CoC with safe limits. Thus, if a chemical falls into the category of potential or identified concern, it will be considered in the next step for determining its exposure potential.

The classification of chemicals into safe, potential CoC, and identified CoC can also be used for prioritizing their management and control. Safe chemicals, deemed to pose no significant risk, do not require immediate prioritization for usage reduction. On the other hand, potential CoC are those that may eventually be classified as CoC. These require proactive management based on the principle that precaution is better than cure. It is more prudent to regulate the use of these chemicals before it becomes mandatory to limit their use through safety restrictions. In this category, prioritization is given to chemicals that are closer to being labeled as CoC, considering their hazardous nature, quantity of use, and the feasibility of reducing their use. Chemicals already identified as CoC with safe limits need to be reduced in use. If their use is necessary, it must be strictly within these limits. Prioritization is typically directed first towards the most hazardous chemicals, followed by the less hazardous ones. This approach requires a coordinated effort on regional, national, and international levels to identify and categorize chemicals. Subsequently, these chemicals are placed on a prioritization list to design strategies aimed at controlling their use and limiting it as much as possible, ideally below the established safe limits. This structured approach helps in mitigating risks associated with chemical exposure and ensures that the most hazardous chemicals are

handled with the utmost care and consideration for public health and environmental safety.

Chemical exposure from a product can occur at any stage of its supply chain. This study defines the exposure potential of a chemical throughout the product's life cycle, including the manufacturing, distribution, use, and end-of-life stages. When evaluating each phase of a product's life cycle, it is crucial to consider the various types of chemical exposure to both humans and the environment. If a chemical is present in the product but does not pose any exposure risk, then that phase does not necessitate consideration for essential use, as the absence of exposure essentially negates the possibility of harm. However, if there is exposure, all chemicals involved in that phase must be assessed and categorized into safe, potential CoC, and identified CoC. In cases where there is both significant exposure and the chemical in question is classified as a potential or identified CoC, there will be a need to apply the essential-use concept. This ensures that the focus is on stages of the product lifecycle where the risk of exposure is highest, thereby prioritizing safety and minimizing environmental and health risks associated with the use of potentially harmful chemicals.

After the scoping phase, if there are unsafe chemicals with potential exposure in the product system, the product system will be analyzed using the essential-use concept. It relates to the function of the chemical within the product, specifically in terms of its relevance to the user. The process begins with an evaluation of the product's essentiality, which involves first determining the intended function of the product. If the chemical's function within the product system does not align with the product's intended function, the chemical can be considered non-essential. However, if the chemical contributes to the product's intended function, it is deemed essential for the product to fulfill its purpose, thereby meeting the essentiality requirement for the product.

If the chemical is essential for the product intended function, then the next phase is to evaluate the functional essentiality, determining whether the function provided by the product is essential to the user. This aspect can be categorized into two types: objective essentiality and subjective essentiality. Objective essentiality implies that the function is crucial to prevent physical or mental harm to the user, underpinning the survivability and functioning of society. Subjective essentiality, on the other hand, suggests that the function may not be necessary to prevent harm but is still considered essential by the user. This distinction is based on personal relevance; what is essential to one user might not be to another. For subjective essentiality, the determination of a function's essentiality may be made by the responsible organization or left to the user's discretion. In contrast, objective essentiality is universally acknowledged and inherently essential. In cases of subjective essentiality, the decision of essentiality can vary based on personal, regional, or national perspectives, depending on the decision-making authority. If no decision is made, the function might still be considered essential based on individual judgment and context. This approach recognizes the varied importance of chemical functions across different contexts and users, highlighting the complexity in determining a chemical's function essentiality in products.

If the product function provided by the CoC is essential, then the next phase is to explore functional alternatives that can fulfill the same function either with absolute or relative safety. In absolute terms, it includes not using the chemical by substituting the function with functional alternatives. Functional alternatives might include using a different chemical within the same product (drop-in substitution), altering the process to eliminate the need for the chemical, or finding a different product or service that achieves the same function without requiring the chemical. These alternatives represent functional substitution at the chemical, process, and product levels. It is important to consider the feasibility and availability of these alternatives within a reasonable acceptability range. If functional alternatives are available, then it will lead to alternatives assessment otherwise it will lead to risk assessment.

In the alternatives assessment phase, the first step is determining the technical feasibility of the alternatives. It centers on applying technical performance standards. These standards serve as benchmarks for evaluating alternatives, ensuring they provide the necessary technical function required for the product's intended use. This "fit-for-purpose" approach prioritizes performance adequacy over finding an exact substitute, focusing on identifying alternatives that meet or exceed specific performance criteria. Such a strategy enables a targeted search for suitable replacements that fulfill the essential functions of the product, streamlining the process of transitioning to safer and more sustainable alternatives. Once the alternatives fulfill the technical performance criteria, the next step is to evaluate whether they are safe to avoid regrettable substitutions. If the alternatives are safe, the final step is to determine whether they are economically feasible. Without economic feasibility, it is difficult to apply alternatives on a large scale. If an alternative is not feasible, it cannot be implemented, and the focus shifts from absolute to relative safety, leading to a risk assessment.

This study integrates risk assessment within the essential-use concept, aligning it with safe limits as outlined in the proposed framework illustrated in Fig. 2. The proposed framework underscores the importance of incorporating risk assessment as a critical component in evaluating the essentiality of use, ensuring that safety considerations are embedded in the decision-making process for managing hazardous substances. Risk assessment involves comparing the chemical's toxicity exposure values with safe limits to determine if it is within safe bounds or not. If a chemical exceeds these limits, its use, although essential, is not permissible as it is unsafe. This necessitates exposure control, innovation or the application of green chemistry to develop a chemical, product, or process that can fulfill the required function safely or reduce the chemical usage to within safe limits. For chemicals that are within safe limits, the goal is to substitute them with relatively safer alternatives at the chemical, process, or product levels. This approach ensures that even when a chemical is essential, all possible measures are taken to minimize risk and enhance safety, thereby balancing the need for functionality with environmental and health considerations.

To understand the proposed holistic chemical management framework of a product system for phasing out non-essential chemical uses, consider a simplified case study of a PFAS-impregnated raincoat. In this example, the product is the raincoat, and the chemical of concern is the PFAS coating. The function of the PFAS in the product is to repel water, acting as a water-repelling agent in the raincoat.

To apply the framework, the first phase involves scoping the system. The initial step is to determine whether the product system contains a chemical. In this case, the raincoat contains PFAS, so it does include a chemical. The second step is to assess whether the chemical is safe. PFAS has been documented as a chemical of concern (CoC), so it is not considered safe and is identified as a chemical of concern. The next step is to determine if the chemical in the product system can lead to exposure. Since PFAS in the raincoat can lead to exposure during use, it has exposure potential. Following this, we need to establish if the function of PFAS—water repellency—is part of the intended function of the product. Water repellency is indeed one of the main functions of the raincoat.

The next phase involves evaluating the functional essentiality of PFAS. This means determining whether the function of PFAS is necessary for the user. Objectively, PFAS is not essential because its absence does not prevent severe physical or mental harm to the user or affect societal functioning. However, subjectively, PFAS may be considered essential for the user's quality of life, providing ease of use by making the raincoat water-repellent. The subsequent phase is to identify whether alternatives are available. There are many alternatives for users to protect themselves from the rain. Therefore, alternatives exist. Next phase is determining functional alternatives. This could involve using another non-PFAS-based water-repellent chemical for the raincoat coating as a chemical alternative, modifying the impregnation process to prevent PFAS release and control exposure, or using a different processing method to make the raincoat water-repellent without PFAS. Other alternatives can be product-based alternatives including

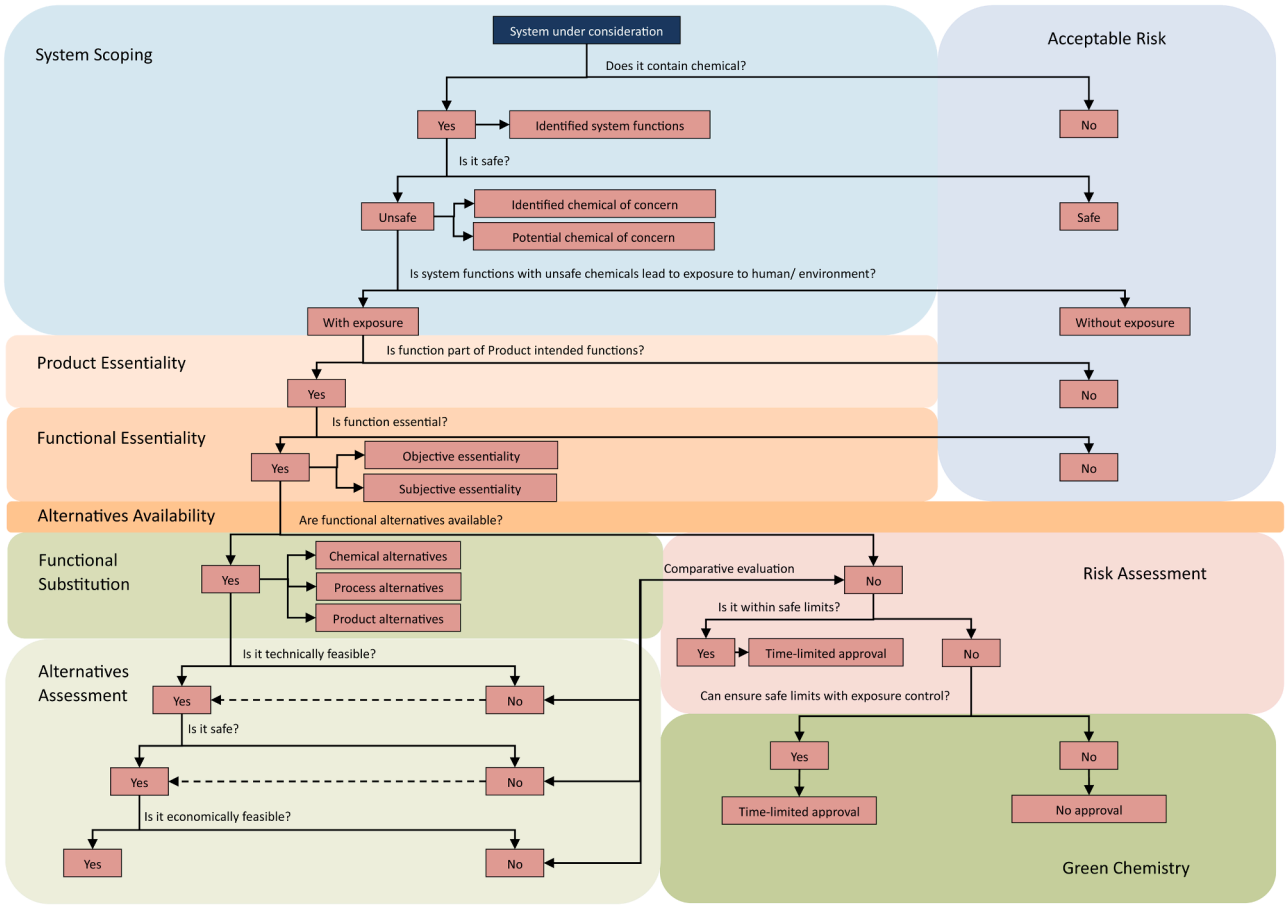

Fig. 2. Holistic chemical management framework of a product system for phasing out non-essential chemical uses.

umbrellas or plastic raincoats.

Once all alternatives are listed, the next phase is to assess these alternatives to determine whether they are technically feasible, meaning they provide an acceptable level of water protection to the user. If the water protection level and performance are acceptable, the next step is to determine if they are safe based on hazard and exposure assessments. For example, using another toxic chemical may lead to regrettable substitutions, meaning it is not a safe alternative. If the alternatives are technically feasible and safe, the next step is to determine if they are economically feasible. If they are not economically feasible, they cannot be applied. If an alternative is feasible, it may replace the product or chemical of concern. However, if no feasible alternative exists, then the product system and all alternatives are compared for relative safety in the risk assessment phase. It compares each alternative risk against safe limits, accepting alternatives that are relatively safe within these limits.

The alternatives will be acceptable for a limited time, with all efforts to find another alternative that is safe and feasible. If there is no alternative within safe limits, and no alternative can be within these limits even after applying exposure control, then it cannot be adopted because it is unsafe in risk assessment. This leads to green chemistry and other innovative strategies to develop safe alternatives to protect users from the rain.

4.2. Safe use vs essential-use

Figuière et al. [25] raise concerns that the "safe use" paradigm could potentially hinder the implementation of the essential-use concept. This is because, under the safe use paradigm, if the risks associated with a CoC are adequately managed, its use is deemed safe, irrespective of the chemical's essentiality. For example, the European Commission may not legally refuse an authorization for non-essential uses if it can be successfully demonstrated that the risks associated with the uses of a SVHC are considered safe [89]. However, this study integrates the safe use paradigm with the essential-use in the proposed framework illustrating that these concepts are complementary rather than contradictory. The incorporation of safe use principles within the proposed framework emphasizes the need for a combined consideration of both safety and essentiality in decision-making processes. This approach suggests that the concept of safe use augments the essential-use framework by ensuring that risk management strategies support the justification of a chemical's indispensability. Consequently, this study promotes a more comprehensive application of the essential-use concept, where safety measures enhance the criteria for assessing a chemical's essentiality, thus contributing to better protection of environmental and human health.

4.3. Chemical grouping in essential-use based framework

The proposed essential-use-based holistic chemical management framework can incorporate the grouping approach in two ways. First, it aids in classifying chemicals into safe, potential CoC, and identified CoC. A chemical may undergo a toxicity evaluation to determine if it is a CoC or not. However, in the absence of data, the grouping of the chemical with similar physicochemical, health, or environmental characteristics can help assess whether it is a concern within the product system or not.

The second application of the grouping approach is in evaluating the chemical through the holistic chemical management framework. If a chemical is deemed non-essential within one product system, similar chemicals used for similar functions in similar product systems may also be considered non-essential. This is based on grouping the essentiality of

chemical use across product systems and applying the grouping approach to assess the essentiality of the chemical for similar potential uses. This strategy can also involves subdividing chemical groups by use categories or functional characteristics, facilitating targeted decisions on the elimination or substitution of specific chemical uses that are determined to be essential or non-essential. For example, if a chemical is used to provide a function that is deemed non-essential within a particular product system, then all uses of that chemical to provide the same function in similar products may be grouped together to determine whether they are essential or not.

Evaluating the use profiles for chemicals in commerce could significantly broaden the scope of risk management by applying a holistic chemical management framework for grouping chemical use in product systems. By assessing one product system to determine whether the function provided by a chemical is essential, all chemicals that are identified as CoC and provide a similar non-essential function within that system could be considered non-essential and may be disallowed for use. By grouping chemicals based on the functions they provide in a product system, the essentiality of these functions can be evaluated. This involves examining the function provided by the CoCs and assessing the necessity of that function across different products. If the function is deemed essential in one product system but not in others, the use of the CoC could be prohibited based on the non-essentiality of the function it provides. This approach allows for a more targeted and effective risk management strategy, where the use of chemicals can be regulated based on the essentiality of their functional contributions to various product systems.

4.4. Limitations of the holistic chemical management framework

There are limitations within the framework, primarily beginning with the product system and determining which chemicals are present [13]. Often, this information is not disclosed by the producer, may be unavailable due to complex supply chains, or is protected as confidential business information [90,91]. However, transparency in disclosing chemical information within the product system is crucial [92,93]. Without it, the product system cannot be evaluated for phasing out non-essential chemical uses. The essential-use concept relies on this information as the basis for chemical management. Without data on the chemicals in the product system, it is impossible to determine whether a chemical is a CoC or not and the framework becomes inapplicable.

To overcome this limitation, while individual product systems may lack specific chemical information, aggregated data across a product class can effectively capture the majority of potential ingredients. Composite ingredient data for a specific product class can support a rapid summarization of product-use categories based on the chemical profile of the product system [94]. Both the U.S. EPA and the European Commission along with other agencies have made efforts to aggregate data on consumer product composition and its chemical profiles [13, 94–99]. However, if a product chemical composition cannot be evaluated, the precautionary principle needs to be applied in society if product information remains undisclosed [100,101]. In cases involving confidential information, the product system might be evaluated by a third-party verifier, or the evaluation might be conducted confidentially and submitted to regulators. However, if information remains inaccessible even under confidential evaluation, the product cannot be considered acceptable for use, regardless of whether it contains essential chemicals or not.

In this study, chemicals are classified as safe, potential CoC, or identified CoC to determine their safety. This classification of a chemical as 'Safe' or CoC requires data. However, for the vast majority of chemicals, there is insufficient data available to make this classification within a given dose range. If there is no information available for a chemical, it will be considered unsafe or a potential CoC as a precautionary measure, and then the essential use framework will be applied. This approach may motivate producers to evaluate the chemical to determine whether it is safe or not, to avoid its classification as a CoC and subsequent evaluation within the framework.

The framework also does not adequately address concerns related to chemical mixtures. Environmental risks of chemicals are still often assessed on a substance-by-substance basis, which overlooks the effects of mixtures and may lead to underestimations of risk [102]. Like other frameworks, it treats chemicals in the product system individually. However, consideration should be given to chemical mixtures with similar modes of action within a product. Each may be below an identified 'safe limit' individually, but their combined additive dose could pose a greater concern. The synergistic effects of different chemicals and their combined impact may result in a different level of toxicity than that of the individual chemicals [103]. The risk assessment process currently faces limitations in evaluating the toxicity of chemical mixtures effectively [104]. In such cases, the chemical mixture should be considered as a single entity, an aggregate of other chemicals with its own unique toxicity profile. There have been attempts to predict the toxicity of chemical mixtures based on the toxicity of individual mixture components or through experiments [102]. With available data, the chemical mixture can be treated as a distinct chemical; otherwise, it needs to be assessed based on the individual chemicals in the product system.

This study applied a 'fit-for-purpose' approach that prioritizes performance adequacy over finding an exact substitute [34]. This approach focuses on identifying alternatives that meet or exceed specific performance criteria. However, it has not been clearly defined who determines what constitutes sufficient performance for substitution. In this study, this primarily raises the question for the product owner, who will decide on the substitution and determine whether the substitution provides the performance that fulfills the production function requirements. In cases where product performance decisions are to be made by a centralized authority or regulators who oversee the product system market, it is the regulator or the decision-making authority who decides the technical performance requirements for the product system to be sold in the market.

5. Conclusions

The concept of "essential-use" is not novel and has seen effective implementation in the past, particularly in regulating the production and use of ozone-depleting chemicals through group-based decision-making. Its consideration is already woven into many chemical regulation frameworks, with recommendations for its broader integration across regulatory contexts. This concept also intertwines with other complementary concepts of chemical management such as CoC, establishing safe limits for chemicals, practicing functional substitution, and implementing alternatives assessment. Furthermore, the integration of strategies like chemical grouping, adherence to green chemistry principles, and considerations of chemical circularity and exposure control are crucial for a comprehensive application of the essential-use concept in a border and holistic chemical management framework of a product system, for phasing out non-essential chemical uses. This study provides an overview of different concepts in relation to essential uses and proposes a streamlined chemical management framework of a product system that links various chemical management strategies. This approach aims to close the gap between technical terminology and public comprehension, facilitating practical, real-world applications of essential-use concept.

Despite ongoing efforts by academics and regulatory bodies to operationalize this approach, peer-reviewed literature on the subject remains sparse, though grey literature in the form of reports is more abundant. For the essential-use concept to be applied effectively, increased data availability and transparency about chemical uses in society are necessary. This study underscores the urgent need for more research to refine the essential-use concept, enabling informed, sustainable decision-making that phases out non-essential chemical uses while considering diverse perspectives and the inherent uncertainties.

Disclosure statement

During the preparation of this work the author(s) used ChatGPT 3.5 in order to improve grammar. After using this tool/service, the author(s) reviewed and edited the content as needed and take(s) full responsibility for the content of the publication

CRediT authorship contribution statement

Rahul Aggarwal: Writing – original draft, Visualization, Validation, Resources, Project administration, Methodology, Investigation, Formal analysis, Data curation, Conceptualization.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Supplementary materials

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Data availability

No data was used for the research described in the article.

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