Environmental Science Processes & Impacts

ROYAL SOCIETY OF CHEMISTRY

CRITICAL REVIEW

View Article Online
View Journal | View Issue

Cite this: *Environ. Sci.: Processes Impacts*, 2021, **23**, 1079

Finding essentiality feasible: common questions and misinterpretations concerning the "essential-use" concept

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Received 4th May 2021
Accepted 23rd June 2021

DOI: 10.1039/d1em00180a

rsc.li/espi

The essential-use concept is a tool that can guide the phase-out of per- and polyfluoroalkyl substances (PFAS) and potentially other substances of concern. This concept is a novel approach to chemicals management that determines whether using substances of concern, such as PFAS, is truly essential for a given functionality. To assess the essentiality of a particular use case, three considerations need to be addressed: (1) the function (chemical, end use and service) that the chemical provides in the use case, (2) whether the function is necessary for health and safety and critical for the functioning of society and (3) if the function is necessary, whether there are viable alternatives for the chemical for this particular use. A few illustrative examples of the three-step process are provided for use cases of PFAS. The essential-use concept takes chemicals management away from a substance-by-substance approach to a group approach. For PFAS and other substances of concern, it offers a more rapid pathway toward effective management or phase-out. Parts of the concept of essential use have already been widely applied in global treaties and international regulations and it has also been recently used by product manufacturers and retailers to phase out substances of concern from supply chains. Herein some of the common questions and misinterpretations regarding the practical application of the essential-use concept are reviewed, and answers and further clarifications are provided.

Environmental significance

Current chemicals management typically relies on risk-based approaches, whereby society performs chemical-by-chemical risk assessments on those chemicals of highest concern, and only those chemicals with demonstrated risks are regulated. Experience has shown, however, that such a time- and resource-intensive risk-based approach is impractical, given the vast numbers of chemicals in use and lack of information on most of them. The concept of essential use argues for a more holistic approach to assessing the use of substances of concern, by asking whether those substances, such as PFAS, are functionally necessary within a given product or manufacturing process. It is argued that substances of concern should only be used if their use is considered essential for health and safety or critical to the functioning of society. If alternatives (*i.e.* different products, materials or chemicals) exist on the market or have been invented, the use of these substances of concern is also non-essential, and can be phased out, though alternatives assessment might be needed. The concept of essential use is not limited to be used by regulators, but can also be used by retailers and manufacturers that aim to reduce their chemical footprint.

Introduction

In June 2019, the concept of "essential use" was recommended as a tool for guiding the phase out of uses of per- and polyfluoroalkyl substances (PFAS) and potentially other harmful "substances of concern".[1] Substances of concern have been defined in the European Union's (EU) Chemicals Strategy for Sustainability[2] as those substances that are harmful for human

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health or the environment, but also those which hamper recycling for safe and high quality secondary raw materials. The question of which intrinsic properties would designate a chemical, or class of chemicals, as "substances of concern" and therefore candidates for application of the essential-use concept is a point of discussion taken up later in this article.

The concept of essential use came up in global discussions concerning how to restrict ozone-depleting substances as early as 1977, well before the adoption of the 1987 Montreal Protocol.[3] The Montreal Protocol codifies the global consensus that a comprehensive phase-out of the production and use of ozone depleting substances is needed to preserve the ozone layer. However, it allows parties to put forward applications for exemptions for those uses considered essential at a national level.

Since the publication of the 2019 paper,[1] there has been a large interest and response. The European Commission was strongly supportive[2,4] and has incorporated the concept in its recently published Chemicals Strategy for Sustainability[2] adopted on 14 October 2020. On the other hand, there has also been strong criticism of the essential-use concept within the chemical industry. Some of these criticisms were recently presented in an article published by Chemical Watch[5] and a statement from the American Chamber of Commerce (AmCham).[6] In our opinion, these criticisms reveal a lack of understanding of the concept, and sometimes misinterpret the concept. Here, we (1) show that similar decision tools to the essential-use concept are already widely applied in global treaties and international regulations, (2) illustrate the application of the essential-use concept for a few case studies, and (3) answer frequent questions, and deal with common misinterpretations, regarding the essential-use concept.

Review of essential use and similar decision tools in chemical regulation

The term "essential use" was defined under the Montreal Protocol in Decision IV/25.19. The two elements of an essential use under the Montreal Protocol are that a use is "necessary for health, safety or is critical for the functioning of society" and that "there are no available technically and economically feasible alternatives". The sectors and uses that came to be considered essential with respect to ozone depleting substances were reportedly agreed upon early in the phase-out process.[4] These included medical uses (*e.g.*, inhalers), laboratory and analytical uses, aerospace applications, firefighting, and a short list of processing agent uses.[7] Notably, Parties to the Protocol did not apply for exemptions for uses related to luxury, convenience, leisure or decorative products. Since the Montreal Protocol, the concept of granting exemptions to certain uses of a chemical has also been included in other international and national regulatory frameworks, such as the EU REACH Regulation,[8] the Stockholm Convention[9] and the EU Biocidal Products Regulation.[10]

In REACH, the use of chemicals may be regulated through authorisation or restriction, for which exemptions (often referred to as derogations) may be considered. For authorisation, companies may apply for continued use of the listed substance after the sunset date, either by demonstrating that the risk from using the substance is adequately controlled (adequate control route), or by demonstrating that the socio-economic benefits of using the substance outweigh the risks and that there are no suitable alternative substances or technologies for the applicant (socio-economic analysis route). For restriction, exemptions are considered during the preparation or the evaluation of the restriction proposal, including a socio-economic analysis. The socio-economic analysis for both authorisation and restriction follows a list of factors that may be taken into account (without excluding any other factors that could be preferred) as specified in REACH Annex XVI. This includes impacts on industry, consumers, job security and employment, and trade, competition and economic development; possible benefits for human health and the environment (and the social and economic benefits, in the case of restriction) and availability, suitability and technical feasibility of alternative substances and/or technologies and economic consequences thereof.

Under the Stockholm Convention, when deciding whether to list a chemical in Annex A (elimination) or Annex B (restriction), the Conference of the Parties (COP) may also decide certain uses to be exempted from the convention obligations. Unlike the Montreal Protocol, the convention does not explicitly specify how exemptions would be decided with which criteria, but only requests specific information to be considered (as specified in Annex F). This includes efficacy and efficiency of possible control measures in meeting risk reduction goals, alternatives, positive and/or negative impacts on society of implementing possible control measures, waste and disposal implications, access to information and public education, status of control and monitoring capacity, and any national or regional control actions taken. There are two types of exemptions, *i.e.* specific exemptions (time limited; for substances listed in Annex A or B) and Acceptable Purposes (time unlimited; for substances listed in Annex B only). Parties to the Convention must register specific exemptions or acceptable purposes, but no justification is needed. The registration of specific exemptions expires automatically after a period of five years, and Parties may apply for an extension, but with a justification of the continuing need for registration of that exemption. To date, no countries have applied for any extension of specific exemptions.

In the EU Biocides Regulation, biocidal active ingredients that fall within the hazard-based "cut-off criteria" for non-approval (*i.e.*, CMR (carcinogenic, mutagenic or toxic to reproduction), PBT (persistent, bioaccumulative and toxic), vPvB (very persistent and very bioaccumulative), or have endocrine-disrupting properties) cannot be approved unless shown to be "essential to prevent or control a serious danger to human health, animal health or the environment" or if there is a "disproportionate negative impact on society when compared with the risk to human health, animal health or the environment". There are no references to safety or the functioning of society.

Illustrating the application of the essential-use concept

In applying the "essential-use" concept to uses of PFAS (or other substances of concern), the following three categories of uses were recommended:[1]

(1) "Non-essential" uses are defined as those driven by convenience and business opportunities and that are "nice to have" rather than having a function that is critical for health and safety, and the functioning of society. An example of a non-essential use of PFAS is their use in providing improved glide to skis through the application of fluorinated ski waxes. PFAS-containing ski waxes may help the skier ski faster compared to when using conventional non-fluorinated ski waxes, but the ability to ski faster is not considered an aspect of health and safety, and the functioning of society. For "non-essential" uses, a phase-out *via* a ban or restriction of PFAS can be prepared (*e.g.* as in the case of the use of PFAS-containing ski waxes in ski racing[11]) without having to conduct time-consuming and costly Chemical Alternatives Assessment (CAA).[12–14]

(2) For so-called "substitutable" uses, the substance of concern does have a function necessary for health, safety or critical for the functioning of society, but its use is considered unnecessary because there are suitable alternatives available. Not all substitutions require direct replacements of a substance of concern with a safer and sustainable chemical alternative; a non-chemical (engineering) innovation can be equally successful and may be encouraged/prioritized over chemical alternatives. For "substitutable" uses, it is important to ensure that the alternatives do not lead to "regrettable substitutions" that lead to "problem shifting" (*i.e.* removing one problem chemical and replacing it with another that is similarly or even more troublesome) and this requires the implementation of CAA.[12–14] The use of PFAS in fire-fighting foams, used for extinguishing fuel fires at commercial airports, is an example of a "substitutable use".[15] The so-called fluorine-free foams (3F)[16] have replaced aqueous film-forming foams (AFFF) for extinguishing fuel fires at commercial airports around the world.

(3) Finally, some uses of substances of concern will be considered "essential" uses because the substance of concern has a function necessary for health, safety or critical for the functioning of society and because there are currently no alternatives. A current example may be the use of PFAS in surgical gowns to provide repellency against a wide range of liquids of different polarities, as well as viruses and bacteria, and to provide breathability of fabrics during long operations.[17] For identified "essential uses", while phase-out is not currently possible, mechanisms need to be implemented to allow eventual transition to safer alternatives. These could include time limits or "sunsets" of a few years set for re-evaluation of alternatives on a regular basis. In the meantime, innovation in the development of safe and sustainable alternatives should be stimulated through, *e.g.*, market incentives, Green Chemistry funding, as well as demand from the public and non-governmental organizations (NGOs). Knowing that once an alternative is developed the substance of concern will be phased out will also drive innovation from the industry sector.

To assess the essentiality of a particular use case and to determine which of the above three categories applies, one needs to consider the following three aspects, in a stepwise manner: (Aspect 1) the function (see definition of "function" below) that the substance of concern provides in the use case, (Aspect 2) whether the function is necessary for health and safety and critical for the functioning of society and (Aspect 3) if the function is necessary, whether there are viable alternatives for the chemical for this particular use. A use of a substance of concern can be considered as "non-essential" when either Aspect 2 is determined to be negative or Aspects 2 and 3 are determined to be positive.

This three-step procedure follows the concept of "functional substitution". When evaluating function under Aspects 2 and 3, one should consider the essentiality of the "chemical function", "end-use function", and "service function", although these different categories of function are not always easily defined and separated.[18]

When assessing the essentiality of the chemical function, an evaluator considers, for example, whether the chemical function and performance provided by the chemical is necessary (Aspect 2) and, if that is the case, whether there is an alternative chemical/technology that can provide adequate function and performance (Aspect 3). Similar questions can be asked for the end-use function, *i.e.* the evaluator asks if the end-use function is needed and, if that is the case, asks whether the end-use function can be replaced by an alternative material, product, or process. In the case of the service function, the evaluator considers whether the service function provided by the chemical is needed, and if that is the case, asks whether the service function can be replaced through system change. The use of a substance of concern would therefore only be considered essential if it was needed on all three functional levels. Functional substitution is described more fully with examples by Tickner *et al.*[18] Below are a few brief examples to illustrate the application of the concept to PFAS.

Occupational protective clothing

The chemical function of PFAS (Aspect 1) is to provide a broad liquid repellency in occupational protective clothing. In this use case, the chemical function and end-use function are closely intertwined. The service function is to protect the health and safety of workers by repelling fluids of a wide range of polarities and, in the case of surgical gowns, avoiding transmission of bacteria or viruses. The service function is needed as is the chemical/end-use function (Aspect 2 positive). In the case of occupational protective clothing, side-chain fluorinated polymers (a type of PFAS) provide both oil and liquid repellency in protective clothing[19] to meet the minimum protection requirements required by performance standards.[20] Currently, because PFAS-free alternatives cannot effectively repel liquids of a wide range of polarities,[17] PFAS-based products continue to be used in many types of occupational protective clothing (Aspect 3, negative). Therefore, the use of PFAS in certain types of occupational protective clothing may currently be considered an essential use.

Non-stick cookware

Certain types of polytetrafluoroethylene (PTFE) and other fluoropolymers may be considered a substance of concern due to the release of numerous PFAS during their lifecycles.[21] In the case of the use of PTFE in non-stick cookware, the chemical function (Aspect 1) provided by using PTFE is the low surface energy (high water and oil repellency), which ensures that food does not stick to the cookware during preparation (end-use function).[22] This function does not protect health and safety (Aspect 2 negative), even if it is convenient, and society can thus phase out its use and reduce the release of PFAS to the environment. Cooking can be conducted without the non-stick function, *e.g.* in cast iron pans. In this case of the non-stick function in cookware, the function can be achieved with sufficient performance by alternatives (Aspect 3 positive). For example, enamelled iron-, ceramic, and anodized aluminium coatings are available.[23]

Cosmetics

In the case of the use of PFAS in cosmetics,[24] the chemical/end use function provided by PFAS (Aspect 1) could be lubrication, spreadability and/or liquid repellency (see *e.g.* results from the POPFREE project[25]). The service function provided by cosmetics may be considered by some important for society in that they contribute to well-being and self-esteem, but they are not critical to health, safety or the functioning of society (Aspect 2 negative). It is noteworthy that in this case PFAS do not contribute to the service function of the product. The chemical and end-use function provided by PFAS can be obtained with chemical alternatives (Aspect 3 positive). Accordingly, multiple brands recently phased out the use of PFAS in cosmetics[26] and are reformulating their products to be PFAS-free.

Multi-component consumer products

Finally, cell phones and cars, which provide critical services in modern society, are known to contain many applications of PFAS in their multiple components.[22] For example, PFAS are used in cell phones in the lithium-ion batteries, the fingerprint-resistant coatings on the screens, the printed circuit boards, the semi-conductors and the fluoropolymer coatings on wiring.[22] To potentially phase out the use of PFAS in a cell phone, one should consider the essentiality of the use of PFAS in each of these individual components, through identification of their function (chemical, end-use and service function) (Aspect 1), whether the function is necessary for health and safety and the functioning of society (Aspect 2) and if the function is necessary, the uniqueness of PFAS for providing that function (Aspect 3).

Common questions concerning the application of the essential-use concept

Here we review and answer some common questions regarding the practical application of the essential-use concept with the aim to provide further clarity for future societal discussion of the concept.

Should we consider certain chemicals as "essential"?

No, we should *not* consider certain chemicals as essential. The essential-use concept is about essential *uses* of a chemical and not about essential chemicals. Chemicals are used to achieve a specific function/performance in a product or process. If a substance used in a specific product or process is identified as being "of concern", then the substance should be removed without substitution (when its use is in fact not necessary), substituted with a chemical that can achieve the same function and adequate performance, or with an alternative technology that does not require the use of the harmful chemical. It is rare that a specific function and performance can only be achieved by one chemical or class of chemicals. Identifying certain chemicals as "essential chemicals" would ignore the original purpose of why chemicals are used, and shift the focus on selling chemicals rather than selling a function/service.

Identifying certain chemicals as "essential" could also be problematic for society because it would lead to the existence of technological monopolies for the economic services provided by the use of a certain chemical or group of chemicals and inhibit innovation. If society then became overly dependent on a chemical or group of chemicals that later were proven to be of concern, it would prove challenging to rapidly phase out these chemicals to eliminate the hazard. History provides many examples of chemicals thought to be essential or indispensable, even though they carried tremendous health and environmental concerns. For example, methyl bromide was long exempted from phase out under the Montreal Protocol as it was wrongly considered indispensable in agricultural production despite serious concerns regarding its ability to deplete stratospheric ozone.[27]

Who should apply the essential-use concept?

Depending on the purpose, an evaluator deciding on the essentiality of a chemical's use could for example be: a regulator working at an agency, a representative of a downstream industrial-user company in charge of chemical stewardship, or the person responsible for procurement at a government authority. The essential-use concept was not developed solely for use in regulation and it may even be more effective as a tool for phase-out of substances of concern in both the private (*e.g.* product manufacturers and retailers) and public (*e.g.* procurement) sectors.

Is the essential-use concept a threat to innovation or an opportunity?

Some critics[5,6] have suggested that the essential-use concept will curtail innovation to discover new convenient functions and performance for products and technologies. It has also been suggested that certain uses of value to society may be considered non-essential and that this will prevent society from benefitting from the convenience or utility of those uses.

However, in actuality the essential-use concept is an opportunity for innovation.

Innovation is key for the development of new materials, free from substances of concern. The essential-use concept will therefore not curtail innovation, but rather channel innovation in the direction of achieving a 'toxic-free environment' and a society where the harm from chemicals and products is minimised.[2] This innovation is desired by consumers, as evidenced in calls for greater transparency[28] and fewer ingredients[29] (in *e.g.* personal care products). In the case of uses of PFAS, many PFAS-free alternatives for a variety of use cases have been developed in recent years (*e.g.* fire-fighting foams,[16] food-contact materials and textiles[19]) due to societal pressure on this class of substances. The phase-out of substances of concern, or the threat of it, has been shown to stimulate innovation to develop new chemicals, materials and alternative solutions.[30] A good example of recent innovation in a collaborative form is within the Swedish POPFREE-project, in which a group of small companies have collaborated to develop alternatives to PFAS for grease-resistant paper, textile and leather treatment, cosmetics, film-forming agents, and fire-fighting foam.[25] Retailers are also increasingly requesting PFAS-free products from their suppliers (*e.g.* Nordic Coop,[31] IKEA[32] and H&M[33]), ensuring increased market shares for the developers of innovative products and materials.

For which uses of which chemicals should the essential-use concept be applied?

The scope of the Montreal Protocol, for which the essential-use concept was first designed, is narrower than that of broad chemicals regulations such as REACH. Under the Montreal Protocol, ozone depletion was agreed as a global threat that defined the scope of the chemicals to be considered. Nevertheless, the broader universe of chemicals includes many substances of national, regional and global concern to which the essential-use concept could be applied. Intrinsic properties of concern such as persistence (P), bioaccumulation potential (B), toxicity (T), endocrine disruptive effects, and mobility (M) are often considered for the broader universe of chemicals to determine which of them are of concern for human and environmental health. The concept of essential use also offers a solution to regulate classes of substances of concern such as PFAS or brominated flame retardants. In essence, the essential-use concept may be used to replace detailed chemical-by-chemical risk assessment. Once a chemical or group of chemicals are designated to be of concern (*e.g.* through growing scientific consensus or regulation), because of problematic intrinsic properties, the essential-use concept would be applied to expediate their phase-out.

In fact, the concept of essential use is exactly *not* needed for chemicals with already identified unacceptable risks, because actions should already be in place to phase out these chemicals. Rather, it is particularly useful for application to chemical classes such as PFAS, which contain thousands of substances, the majority of which have not undergone detailed toxicological assessment, yet all have one or more problematic intrinsic properties.

Although there may not be consensus on what is considered a "substance of concern" or class of substances of concern, the essential-use concept is flexible and can be applied to a broad range of chemistries. Application of the essential-use concept on a class basis would avoid unnecessary exposure of humans and the environment to a whole class of chemicals. This is also articulated in the Chemicals Strategy for Sustainability of the EU,[2] for example in Section 2.3.1 "move away from assessing and regulating chemicals substance-by-substance to regulating them by groups". The essential-use concept is intended for managing "substances of concern" because for these substances a speedy replacement and/or effective mitigation measures are particularly important.

Which uses of chemicals are critical for the functioning of society?

Uses of chemicals that protect human health and safety are relatively easy to identify. In the case of uses of chemicals that are "critical for the functioning of society", more detailed analysis is required and potential use categories include those uses that, for example, support the basic conditions for human life, such as providing sufficient and clean food, water, shelter and security. This list of use categories is not intended to be exhaustive or conclusive because each organization or jurisdiction applying the concept will need to make their own judgement on which uses qualify as critical for the functioning of society. Social scientists may need to be employed to identify these categories (*e.g.* through surveys of various stakeholders in the population), while at the same time the identification of categories should be balanced against the long-term societal costs of continued use of substances of concern.

What is the role of technical performance standards?

Technical performance standards, *i.e.*, detailed specifications concerning how a product should perform, may play a role in defining whether the use of a substance of concern is considered "substitutable" or "essential" (*i.e.* do alternatives provide suitable performance?). If the use of a non-hazardous alternative can achieve adequate fit-for-purpose performance for a specific function, the use of the substance of concern can be considered "substitutable" and no longer "essential". For example, fluorine-free foams (3F)[16] have been shown to provide sufficient fire extinguishing performance at commercial airports around the world such that they have now replaced PFAS-containing aqueous film-forming foams (AFFFs) for extinguishing Class-B fuel fires. Regional (*e.g.* US *versus* EU) and sector-based (*e.g.* military *versus* commercial airports)[34] differences in technical standards may still exist, which might lead to regional and intersectoral differences in essentiality determinations.

Technical performance standards can unfortunately also require the use of substances of concern without scientific justification, and may create technical lock-ins that inhibit their phase-out. For example, in the US, concern over fires caused by cigarettes led to a flammability standard for the polyurethane foam used in upholstered furniture. The most cost-effective way

to achieve the standard was by the addition of high levels of hazardous organohalogen flame retardant chemicals to the foam. Efforts to change the standard due to concerns regarding the human and environmental health effects associated with the flame retardants were impeded by the manufacturers of the flame retardants for years. Eventually a new standard was developed that ensured fire safety without the addition of harmful chemicals. This resulted in the lowering of indoor air/dust concentrations of flame retardants.[35]

Another example of a standard inhibiting the phase out of PFAS is the U.S. Department of Defense (DOD) military specification (referred to as "Mil-Spec") that required the firefighting foams used for extinguishing Class-B fuel fires to contain fluorine or have positive spreading coefficients necessary for film-formation.[16] The Mil-Spec standard was also extended to civilian airports by the US Federal Aeronautics Agency. Over the past couple of decades, fluorine-free foams (3F) were developed that matched the performance of many AFFF in extinguishing fuel fires. However, because they did not contain fluorine, they could not achieve Mil-Spec approval. Due to recent legislation enacted by the US Congress, civilian airports and DOD installations are no longer required to use fluorinated AFFFs. The use of fluorinated AFFFs has left a legacy of hundreds of instances of PFAS contamination of groundwater and drinking water across the United States[36] and elsewhere.

Are there regional and temporal differences in essentiality and is this problematic?

Similar to the differences in the essentiality of human and commercial activities during the COVID-19 pandemic, it is likely that there will be inter- and intra-regional differences in what is judged to be an essential use of a substance of concern. It is well known that there are currently large inter-regional differences in how chemicals are regulated (including *via* technical standards, as stated above) that depend on politics and other factors, and it is unlikely that the application of essentiality will be any different. As well as political differences, geographical differences can also lead to different conclusions regarding essentiality.

The view that it is highly subjective to determine which uses are essential or not was put forward in a recently published commentary written by a representative of the chemical industry.[5] The COVID-19 global pandemic was used in the commentary as an illustrative case to point out that different countries come to different decisions on what are essential and non-essential human and commercial activities during extraordinary circumstances such as pandemics. It has further been argued that if society had determined that the use of PFAS in personal protective equipment (PPE) was non-essential before the COVID-19 pandemic, it would have left humanity vulnerable to COVID-19. In other words, the pandemic has been used to illustrate that there can be regional and temporal variations in essentiality.

The EU Plant Protection Products Regulation (PPPR)[37] is an example of regional differences concerning what might be considered essential. Under the PPPR, approval of an active substance takes place at the EU level, after the substance has been assessed to make sure it meets certain criteria. Authorization of the formulations ('products') using the approved active substance, on the other hand, takes place at the Member State level. To ensure the free movement of goods within the EU and reduce administrative burdens, the PPPR applies the principle of mutual recognition, under which authorizations granted by one Member State are to be accepted by other Member States. During the legislative process, this principle of mutual recognition was strongly resisted by the Nordic countries, because of differences in geographical conditions with *e.g.* the Mediterranean countries. The impasse was resolved by dividing the EU into three geographical zones with comparable agricultural, plant health and climatic conditions that are key factors regarding the presence of pests and in pesticide degradation, *i.e.*, North, Centre and South. The principle of mutual recognition applies within each zone, but not across zones. Although it is likely that regional differences in the perceptions of essentiality of a use will exist, this does not preclude the use of the essential-use concept as a tool to guide the phase-out of substances of concern.

With regard to temporal variations in essentiality, it is hoped that for uses for which a substance of concern is still essential today, more sustainable alternatives will be developed in the near future and the substance of concern will no longer be needed. On the other hand, cases where substances of concern are non-essential today and essential tomorrow are likely to be rare but are possible (*e.g.* due to a sudden increase in malaria in a region or during another unforeseen pandemic). Fortunately, chemical legislation often contains a clause on emergency approval for chemicals. Therefore, when special circumstances arise, exceptions could be made, but this does not justify the non-essential use of substances of concern outside of times of crisis.

How is the application of the essential-use concept in chemical regulation currently being done or discussed?

Discussions about applying the essential-use concept are currently primarily taking place in Europe, where there may be opportunities to apply the concept in the REACH Regulation.[8] Equivalent opportunities for integrating essential-use ideas have not been identified within the chemicals legislation for the US though discussions about applying the concept are under way at the state level.

A recent discussion paper for CARACAL (Competent Authorities for REACH and CLP)[4] discusses possibilities for applying the essential-use concept within EU chemicals regulation. The paper points to the lack of reliable and specific information on the costs and benefits of each particular use of an SVHC, a problem frequently confronting those preparing an authorization or restriction dossier. It suggests that the concept of essential use could enable a faster processing of authorization and restriction dossiers, by taking into consideration the essentiality of a particular use early on.

Notably, a version of the essential-use concept is already integrated in China in the newest version of the new chemical

registration law that entered into force on 1 January 2021, in a different direction from the considerations under REACH as stated in the CARACAL discussion paper.[38] In particular, it specifies that for highly hazardous substances (*i.e.*, PBT or vPvB substances, or substances of equivalent concern to the environment or human health), registrants must submit information on socio-economic benefits of the chemicals to fully justify the necessity of the intended activities (*e.g.* research, production, import, processing and use). The socio-economic benefit analysis includes whether the new chemical substances are equivalent to or have obvious advantages over the substitutes that are in use in terms of aspects such as performance and environmental friendliness. The registration will be evaluated by an expert committee and competent authorities; if rejected, then the chemical cannot be used in the intended activities in China. Along with the new chemical registration law, an implementation guidance, including detailed requirements of the socio-economic analysis, has also been published.[39]

How can regrettable substitutions be avoided?

Concerns have been raised that the rapid phase-out of a class of substances of concern (*e.g.* PFAS) due to application of the essential-use concept will potentially lead to regrettable substitutions.[4] However, even if a use case of a substance of concern is deemed "non-essential" or "substitutable", this is only the first step in the assessment process. For "non-essential" uses, the use does not require substitution, given that the use has no essential function. In the case of "substitutable" uses the next step is to identify and evaluate functional alternatives. The scientific discipline of CAA[12–14] offers established and evolving methodologies for comparing and selecting safer alternatives to substances of concern. If these procedures are properly followed, and the uncertainties intrinsic in CAA are properly considered, regrettable substitution should be minimized.

There is a possibility, however, that there may be a lack of information on hazardous intrinsic properties for some alternatives that could add uncertainty to the substitution process. For example, brominated flame retardants were replaced with supposedly safer organophosphate ester flame retardants, but little was known about these alternatives and research projects were needed to fill data gaps.[40] Now evidence is mounting that these alternatives are also problematic.[41]

An example for PFAS is the case of replacing PFAS-containing products for durable water repellency in textiles with PFAS-free alternatives. It was found that is some cases there is far less information for PFAS-free alternatives compared to the PFAS-based products.[19] A lack of information on alternatives does not imply that a regrettable substitution will occur, but it does increase the possibility. It is the responsibility of product manufacturers, in the EU at least, to assess their products before putting them on the market and this could be substantially improved if they better inform scientists and the public of the chemical content of their products so that proper chemical assessments can be undertaken and regrettable substitutions avoided. However, while some substitutions were made purely because effects were unknown at the time, others may have occurred due to a lack of due diligence – where for instance effects of endocrine disruptions were well known, but not tested for. With the inclusion of more hazard endpoints (*e.g.* endocrine disruption, neurotoxicity, immunotoxicity, respiratory toxicity, sensitisation and terrestrial ecotoxicity) and intrinsic properties (*e.g.* mobility) as properties of substances of concern under the EU's Chemicals Strategy for Sustainability, the aim is to decrease the likelihood of such regrettable substitutions in the future.

Concluding remarks

The essential-use concept is used already by some product manufacturers and retailers, as well as in public procurement, to make decisions on whether the use of a substance of concern is appropriate. Considerations of essentiality of uses are also integral in many existing legal frameworks for chemical regulation (*e.g.* the Montreal Protocol, the EU REACH regulation, the EU Biocidal Products Regulation, and the Stockholm Convention) and it has been suggested[4] that its further integration within REACH could potentially speed up the authorization and restriction of substances of concern. The ability to limit the use of substances of concern in general, and PFAS more specifically, is a priority for recent actions such as the EU's Zero pollution ambition initiative, as well as the move towards a circular economy.

Much work is already underway, in particular by academic and regulatory scientists, to determine how the approach can be implemented in practice. The action plan of the European Commission's Chemicals Strategy for Sustainability[2] indicates, for example, that the criteria for essential uses will be defined in the period 2021-22. In this article, the responses to common questions have demonstrated that many of the challenges for the further implementation of the concept are not insurmountable. Despite the criticisms of the concept that have been conveyed, largely by manufacturers of chemicals at risk of being phased out, essentiality of uses as a concept is feasible. Appropriate application of the essential-use concept will furthermore require more information and transparency regarding the uses of chemicals in society, which is a positive development.

Author contributions

Ian Cousins led the writing of the manuscript. All other co-authors contributed valuable content through in-depth on-line oral group discussions and through commenting and editing multiple drafts.

Conflicts of interest

There are no conflicts of interest to declare.

Acknowledgements

The authors thank the Global PFAS Science Panel (GPSP) and the Tides Foundation for supporting this cooperation (grant

1806-52683). Ian Cousins acknowledges funding from the Swedish Research Council for Sustainable Development (FORMAS) (grant 2020-01978). Rainer Lohmann acknowledges funding from the US National Institute of Environmental Health Sciences (grant P42ES027706); Martin Scheringer acknowledges funding from the CETOCOEN PLUS project (CZ.02.1.01/0.0/0.0/15_003/0000469), the project CETOCOEN EXCELLENCE (No. CZ.02.1.01/0.0/0.0/17_043/0009632) and RECETOX RI (No. LM2018121) financed by the Czech Ministry of Education, Youth and Sports. We thank Apolline Roger (ClientEarth), Joel Tickner (University of Massachusetts), Andrew Lindström (US EPA), Lena Vierke (German Environment Agency) for valuable discussions and Georg Sojer for help with the graphical abstract. The views expressed in this article are those of the authors and do not necessarily represent the views or policies of the European Environment Agency.

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