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**Review of scientific and methodological data
on the concept of essential use, with PFAS as
a case study**

PREAMBLE

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Summary

This report examines the essential use concept (EUC) in the context of chemical risk management, focusing specifically on PFASs (per- and polyfluoroalkyl substances). It presents the current regulatory context, the actions underway within the European Union and in France, and an analysis of the scientific and methodological data relating to this concept of "essential uses". The report also discusses the steps involved in implementing this concept proposed by the European Commission and provides an illustrative application to the uses of PFAS.

Since 1987, the EUC has formed the basis of the Montreal Protocol on Substances that Deplete the Stratospheric Ozone Layer, although the literature specifically concerning it is fairly limited and recent. As a result, the scientific and technical, as well as political, ethical and social, issues raised by the EUC have been little addressed in the context of chemical risks, in favour of the development and operational use of concrete criteria. Recently, the importance of implementing (or even creating) forms of consultation and social construction to seek shared definitions of the EUC has emerged.

The essentiality criteria proposed by the European Commission in April 2024 are accompanied by descriptions that are much more detailed than those used in the Montreal Protocol, but which are still largely open to interpretation. In terms of process, the proposal relies heavily on existing REACH expert assessment tools, the analysis of alternatives, and, more implicitly, on socio-economic or risk/benefit assessment. The analysis of alternatives in REACH has encountered problems related to access to data, and it has proved difficult to assess the economic and technical feasibility of alternatives. It could therefore remain a limiting factor for the implementation of the EUC as proposed by the EC. Socio-economic analysis, despite methodological difficulties, can be a complementary tool to the EUC, to take into account the consequences of applying essentiality criteria.

As regards application to PFASs, introducing the essentiality criteria proposed by the EC does not seem to substantially alter the proposals (and their ongoing examination by ECHA) made in the context of the "universal" restriction of PFASs under REACH. This could be seen as an indication that either the EUC is already implicitly taken into account by all the players involved in the restriction, or that the analyses of alternatives and socio-economic consequences are the ones driving the conclusions.

Even if this conclusion regarding PFASs could be generalised (which would require a retrospective analysis of other past restrictions under REACH), the EUC could remain a tool providing additional resources for prioritising chemical risk management measures, a possible acceleration of their implementation by supporting certain decisions, and a means of increasing their transparency through decision criteria that are readable by all, and less technical than those of a socio-economic analysis.

If it is decided to implement the EUC, a number of suggestions can be made regarding its implementation:

- Pursue studies and research to improve knowledge of this concept, which is still relatively under-researched, in particular through retrospective studies, but also by continuing this work, which is still generic in its application to PFAS (for example, in a high-stakes sector such as energy);
- Work on the methods and tools for involving stakeholders or citizens in the development and implementation of criteria, going beyond the expert assessment procedures in place under the REACH regulation;
- Study the way in which the EUC can be combined with current expert appraisal tools, for example in a "qualitative/weight of evidence" approach.

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1 Introduction

As part of Action No. 11 of the 2024 Interministerial Action Plan on PFAS "Distinguishing essential uses from non-essential uses", Ineris was asked to carry out **a review of the scientific and methodological data on the concept of "essential use" (Essential Use Concept, EUC), with PFAS as a case study.** This work constitutes the Ineris deliverable for this action.

After recalling the regulatory context of demand in the field of PFAS, this report summarises the scientific literature on this concept and related concepts, followed by a review of the concept of essential uses in current and past chemical regulations. We then describe and discuss the critical points of the stages in a possible procedure for implementing the concept of essential uses¹, as recently proposed by the European Commission. We conclude this report with an illustrative application of this proposal to PFAS uses, and comment on the results obtained.

¹ Or "utilisation" in the French translation of the European document. We will mainly choose "uses" in this report, as this term seems to us to be more frequently used, but the two terms seem to us to be interchangeable.

2 The context of this report

2.1 Chemical risk management context

The impact of exposure to chemicals on health is difficult to assess, but could be significant. Publications that have made expert estimates of the fraction of disease attributable overall to chemicals suggest a wide range, up to 40% (HCSP, 2022). Managing the risks of chemicals is a difficult challenge because of the sheer number of chemicals and the variety of routes of exposure. Public action is focused on assessing the risks of individual chemicals (and, where possible, dealing with larger, more recent groups), followed by regulatory action. However, a large number of chemicals in use remain unassessed or incompletely assessed in terms of risk or hazard, and management decisions are sometimes deemed to be too slow and lacking in transparency (European Ombudsman, 2024). After 18 years of application, the REACH regulation has led to improvements, but it has also shown its limitations and is regularly the subject of studies and proposals for improvement, particularly from the European Commission itself (study on the reform of REACH and the introduction of "Generic Risk Management", studies underway on the promotion and organisation of support for the substitution of chemicals, communication on the Chemical Strategy or the "Zero Pollution Action Plan"). Preventive measures to raise consumer awareness and provide information, and the development of "*safe and sustainable by design*",² have also been initiated, notably by the European Union and industry. However, work on "*safe and sustainable by design*" (SSbD) is still mainly focused on researching and testing less hazardous chemicals, and does not really address the use of chemicals (Brignon J.M., 2021).

Faced with this situation, a parallel movement has been emerging for several years, which aims to question more directly the appropriateness of the use of hazardous chemicals and to limit their use, promoting the concept of "essential uses", which had previously remained relatively confidential. The aim of this part of the report is, after an introduction to PFAS and their management, to introduce, situate and describe the concept and its potential applications from a scientific and methodological point of view.

2.2 The problem of PFAS management

Per- or polyfluoroalkyl substances (PFAS) are a large family of several thousand chemical compounds. According to the definition produced by the OECD, these are molecules made up of a chain of carbon atoms of varying lengths, linear, branched or cyclic, and containing at least one fluorinated group, either methyl or methylene, saturated and completely fluorinated. Various functional groups can be added to this fluorocarbon backbone, giving these molecules distinct physical, chemical and toxicological properties. They have a number of properties (non-stick, waterproofing, heat resistance) that have encouraged their manufacture and subsequent use by a wide range of industries since the 1950s. PFASs are very persistent molecules, widely distributed in the environment and bioaccumulative. The properties (physicochemistry, toxicity, ecotoxicity, etc.) of certain PFAS molecules (PFOA, PFOS, etc.) are well known. For these few molecules, the knowledge available has already led to the implementation of regulatory measures. For the vast majority of other PFAS, knowledge is patchy (or even non-existent), but the extreme persistence and already known hazards now call for a heightened level of vigilance and action with regard to all substances meeting the OECD definition. The problem of PFASs is therefore a complex one, with major socio-economic implications, which explains why it has prompted a debate on chemical risk management and the concept of essential uses.

2.3 Actions underway in the EU and the French government's action plan

The proposal to regulate PFASs is a long-standing one: the 2015 Madrid Declaration, formulated by a college of scientists, proposes regulating the use of PFASs by essential uses (Blum A. et al, 2015). In 2019, the Council of European Environment Ministers is calling for an action plan to eliminate non-essential uses of PFAS.³

A specific REACH restriction, which has already been evaluated by the ECHA committees and is currently being examined by the European Commission, should ban PFASs in fire-fighting foams. Other

² safe and durable by design

³ Council conclusions OUTCOME OF THE COUNCIL MEETING 3705th Council meeting Environment Luxembourg, 26 June 2019 http://data.consilium.europa.eu/doc/document/ST-10713-2019-INIT_en

REACH restrictions have previously been adopted by the EC concerning certain types of PFAS, such as PFOAs, PFHxA and PFHxS.

A proposal for a "universal" restriction of PFASs under REACH, based on the broad definition of molecules qualifying as PFASs proposed by the OECD and covering all application sectors except those not covered by the REACH regulation, is currently being assessed by ECHA's expert committees.

Other European regulations and directives are also concerned by proposed bans on PFAS: food packaging regulation⁴, toys regulation, cosmetics regulation.

In 2023, the French government launched a **ministerial action plan**. Action No. 11 of the plan involves distinguishing between essential and non-essential uses of PFAS. This report is part of this action. The context of this report also includes French support for the 'universal' restriction of PFASs at European level under REACH (action no. 10).

Following the publication of the action plan, the government commissioned a report from MP Isaac-Sibille⁵ to "update and complete the diagnosis of the situation in France (uses, environmental contamination), take stock of knowledge of PFAS impregnations in the various environments and study the essential nature, or otherwise, of some of these compounds for technologies that are crucial to the ecological transition". This report proposes to study the use of the concept of essential uses (EUC) in the request for REACH restrictions on PFAS. However, this proposal does not provide any details or method for implementing the EUC. The report, submitted in February 2024, proposes in its recommendation no. 11 to "distinguish the essential from the superfluous and take rapid decisions concerning the superfluous". It therefore proposes that the concept of essential uses (CUE) be taken into account in the request for REACH restrictions on PFAS. This proposal does not, however, provide any details or method for implementing EUC in the report.

In April 2024, the French government launched an **interministerial action plan on PFAS**, integrating and substituting the actions set out in the 2023 ministerial plan of the Ministry of Ecology on the same subject. Actions 10 and 11 of the ministerial action plan have been identically incorporated into the interministerial action plan.

2.4 The Thierry Bill

On 20 February 2024, Nicolas Thierry, Member of Parliament, tabled a bill to address the risks associated with per- and polyfluoroalkyl substances. The aim of this bill is to introduce legislation in France ahead of the process of requesting restrictions under the REACH regulation, which is currently being examined at European level, but which is not expected to be completed until 2028. The restrictions will be effectively phased in from 2029-2030, and the phasing-in will likely continue until around 2043 for sectors benefiting from temporary derogations.

The initial proposal for the law provided for a general ban with exemptions. Conversely, the changes made to the text during the parliamentary scrutiny process limit the restrictions to uses on a positive list. The exemptions take account of the purpose of the use (health, civil protection and defence equipment) but also other factors, probably economic (food contact materials). Among the uses removed from the scope of the bans as a result of the switch to a positive list are plant protection products. The concept of essential uses has probably played a role in these changes, albeit an implicit one, which highlights the need for methodological work on this concept.

3 The concept of essential uses in the literature

In this section we will analyse the concept of essential uses and related concepts in the scientific literature. As will become apparent, the specific literature on the exact term "essentiality" is fairly limited and recent. As a result, our exploration of the literature will focus primarily on related concepts, starting with the concept of "sufficiency", which is more widely discussed in the literature, and which may help to shed light on the conceptual and methodological aspects of essential uses.

⁴ See https://www.europarl.europa.eu/doceo/document/TA-9-2024-0318_EN.html

⁵ <https://cyrille.isaac-sibille.fr/mission-gouvernementale-pfas/>

3.1 The concept of sufficiency

In 2022 (IPCC, 2022), the IPCC defined the concept of sufficiency as follows "Sufficiency policies are a set of measures and daily practices that avoid demand for energy, materials, land and water while delivering human well-being for all within planetary boundaries". Sufficiency is defined in terms of quantities and is therefore distinct from essentiality, which is expressed in qualitative terms, but these two concepts share the fundamental idea of an action on behaviour and of limitation or regulation different from that of the supply/demand interaction. It is close to the term 'sobriety' (energy, digital, etc.), which is also often used in French, and has been the subject of numerous publications, both theoretical and applied (Jungell-Michelsson J. et al., 2022), whereas the concept of essentiality remains confidential and limited to a few areas: chemical risk, 'essential' workers (a subject that became topical again during the COVID-19 pandemic)⁶. Before the recent emergence of "essential uses" of chemicals, studies had also defined and questioned the notion of "essential goods (or services)". This concept has some similarities with "sufficiency", but more explicitly marks a delimitation between essential and non-essential categories. Healthy food, decent housing, education, health⁷, the ability to use transport, etc. are often described as essential. In the first instance, these are seminal works whose motivations are the fight against poverty and justice (Davis B., 2023), with an extension to the issue of the fight against climate change.

Essentiality and sufficiency have in common a limitation of individual freedom in order to preserve common goods, and several disciplines and numerous researchers have more recently been reflecting, after economist Amartya Sen and philosopher John Rawls in particular, on the ethical, economic and philosophical foundations as well as the political and societal issues for their concrete implementation. For example, (Princen T., 2022) argues that only a reorganisation of society currently structured around the notion of consumption, productivity and growth, which he considers incompatible with sufficiency, can bring about change. Without necessarily advocating radical change, several authors working on 'sufficiency', including (Gough I., 2023), advocate explicit societal dialogue as an alternative to the implicit fixing of needs by the 'law of supply and demand'. In this vision of sufficiency, people no longer seek to maximise their well-being, but at least to be in a 'tolerable' position, and if possible to achieve a state of 'contentment' (Davis B., 2023). In this sense, the concept of sufficiency presents a certain radicalism in relation to current economic theories and organisation, and despite a significant literature, it is generally regarded as a radical and very minority trend among economists 'in action' (Jungell-Michelsson J. et al., 2022). Reflections of this radicalism can be found in certain positions taken by industrial players, who consider that the proposals on "essential uses" are in contradiction with the market economy and risk undermining its effectiveness in bringing well-being, and prefer the concept of "safe uses" (Corporate Europe Observatory, 2024).

The 'sharing economy' has also borrowed from, or contributed to, the spread of the concept of sufficiency or essentiality, in that it can use it as a foundation and analyse its own contribution to a moderation of individual needs (Ivanova D. et al., 2023).

3.2 The concept of essential uses

While it is very important in the field of psychology or philosophy, the concept of essentiality itself has been the subject of relatively few publications in the field of risk management. The articles dealing with the subject (Cousins I. et al., 2019) (Cousins I. et al., 2020) (Cousins I. et al., 2021) (Roy M.A. et al., 2022) (Figuière R. et al., 2023) take up the definition of the Montreal Protocol but do not question it and discuss more the link between EUC and other risk management subjects (analysis of alternatives) or propose concrete roadmaps and decisions applied to PFAS. There does not seem to be a method that can be transposed to various sectors or chemicals. For example, (Cousins I. et al., 2019) develops a

⁶ As far as 'essential workers' are concerned, while at first sight the definitions adopted resemble those of essential uses ('workers critical to the functioning of society'), it has generally been found that, in practice, most economic sectors and actors have come to be regarded as essential, the essential being in fact to maintain the maximum level of economic activity (Collins J., 2023). While this has had the merit of raising awareness of the importance of 'invisible' or poorly-paid jobs, there has been little in-depth questioning by social actors of the 'essentiality' of the various services or consumer goods to which these 'essential' workers contribute.

⁷ See the concept of "essential" medicines, which is well documented in the literature, but which is very specific to this field and which we are not analysing in the context of this report.

classification of PFAS uses between essential and non-essential, based on an interpretation of general criteria that is not the subject of any real methodological work.

(Karinen A.K. et al. 2024) (Sulfill E., 2024) and (Bălan S. et al., 2024) focus on implementation issues to which we return below (3.3). (Montfort J.-P., 2021) deal mainly with legal aspects and propose that essential sectors should be set on the basis of sectors that the EU has deemed "strategic", which would link essentiality to economic growth and well-being and tend to obscure the problem of conflicts between these economic/strategic objectives and the "zero pollution" objectives that the EU has set for itself.

Overall, these publications offer few elements in terms of theoretical foundations or evaluations and proofs of concept. It would therefore appear that the EUC has already been implemented in the Montreal Protocol for several decades before it began to be the subject of scientific debate. The political, ethical and social issues raised by the "sufficiency" theorists have been little addressed in the context of chemical risks, in favour of the development of concrete criteria. Outside the Montreal Protocol, the concept has continued to be applied (albeit implicitly, without yet being called essential), but only marginally, through recent restrictions on certain perfluorinated substances (PFOA, PFAS in fire-fighting foams) under REACH. These restrictions include exemptions for uses designated as critical to safety or public health.

3.3 Involving citizens, comparing risks and benefits

In terms of methods and procedures for implementing the concepts of sufficiency or essential uses, a certain consensus seems to emanate from the research world to stress the importance of implementing (or even creating) forms of social consultation and construction to seek shared definitions (Karinen A.K. et al. 2024) (Sulfill E., 2024) (Bălan S. et al., 2024), in place of or in addition to market mechanisms⁸. There is the same near-consensus in stressing the difficulty of finding common definitions or common thresholds, as the variability of judgements is significant and has multiple sources (Karinen A.K., 2024) and in particular cultural sources (Sulfill E., 2024). For example, it had already been noted at the time of the Montreal Protocol that air conditioning could be seen as essential or accessory depending on the context (Garnett K. et al., 2021). It should also be noted that the Montreal Protocol considers that certain hazardous substances may be necessary because they are essential not only for the "functioning of society" but also for "cultural and intellectual" reasons. The inclusion of these dimensions seems legitimate but is likely to amplify the problems of definitional variability. The cultural dimension is included in the Commission's recent Communication on the EUC, C/2024/2894, which proposes more detailed descriptions of the criteria derived from the Montreal Protocol. These descriptions still leave open the problem of thresholds between "essential" and "non-essential", and how to agree on them in an accepted and sustainable way, or the question of conflicts between "essential" and the "green and digital transition".⁹

There is therefore a need for development and experimentation in the practical implementation of essential use criteria. One proposal, which is still fairly generic, put forward in (Sulfill E. et al., 2024) is to avoid expert judgements, to embrace the variability of perceptions, by basing choices on large-scale, systematic and representative surveys conducted directly among citizens. On the other hand, some believe that cost-benefit analysis alone, based on the notion of well-being, should continue to be the only method for arbitrating between risks and benefits - see (Montfort J.-P., 2021) and the positions reported in (Corporate Europe Observatory, 2024). Others think that cost/benefit or risk/benefit analysis should continue to be used alongside essential use criteria (Karinen A.K., 2024), without specifying how they should be combined, and some consider that it should be abandoned (Princen, 2022). Without making a decision, it is clear that the two tools are two contrasting approaches (welfare economics, focusing on the consequences of options for costs/benefits and risks/benefits; whereas focusing on principles and a social norm for essential uses) which we will have to decide whether they are exclusive or complementary, and if so, how they should be combined. This important point is illustrated by the debates on health in the European workshops organised recently by the consultant WSP for the EC. WSP proposed a fairly narrow definition of health, based on basic needs, and some emphasised the

⁸ In this respect, it should be noted that researchers working in this field generally either do not know about or do not believe in (Princen, 2022) the capacities of market regulation mechanisms such as financial instruments (pollution taxes), even though such tools seem to have the approval of a majority of citizens according to a study by J. Lage (carried out in the context of the fight against climate change) (Lage J. et al., 2023).

⁹ We will examine their possible application to PFAS in the final chapter of this report.

desire to adopt a broad definition of 'one health' based on the WHO. According to (WSP, 2024), industry - perhaps concerned with a broad application of essentiality - is in favour of a broad definition of health, whereas other public players, responsible for managing health/environmental risks and usually more in favour of a broad definition, seem to favour a restrictive definition in this context. To resolve this divergence, the debate organised by WSP brought to the fore the expression of a need for risk/benefit or cost/benefit assessments, which in contrast some believe the concept of essential uses is supposed to avoid. The same fundamental divergence emerged during the debates on cultural aspects and, more generally, on the ways of deciding on "criticality for society".

In the absence of a systematic proposal, the literature nevertheless provides examples of cases and configurations that can help implement the concept of essential uses:

- The cases in which the level of performance may be unnecessary, or over-prescribed, would be cases of "non-essential" uses. For example, certain standards may prescribe the use of certain chemicals instead of focusing on the level of performance and its justification (Roy M.A. et al., 2022). This problem has already been identified as a potential obstacle to substitution under REACH, for example in the case of aesthetic or functional performance requirements for chrome-plated parts, but little action has been taken to resolve it. The case of "consumer" technical sportswear with resistance performance in environments reserved for professionals is also often mentioned (Roy M.A. et al., 2022)¹⁰ ;
- One example is ski wax containing PFAS, which (very marginally) improves the sporting performance of professional skiers. An agreement or regulation covering all professional skiers demonstrates that the service provided is not essential and that the substance can be banned for this use. This case has been used in the context of recent and ongoing REACH restrictions on PFAS.

Ultimately, we find that the concept of essential uses cannot currently claim to be validated scientifically or by consensus, or to be fully applicable today for deciding on the use of substances. Assessments remain open to interpretation and dependent on societal choices, while the governance framework for managing this aspect has not been prepared.

In the remainder of this report, we present examples of the use of the EUC in the regulation of chemicals in a more systematic way, and then describe the main choices and methodological problems that would arise for a possible implementation of the EUC on the basis of the European Commission's proposal.

4 A brief history of essential uses in chemicals regulations

The call for PEC was first identified in 1978 in amendments to the US Toxic Substances Control Act, which banned aerosols containing hazardous substances in "non-essential" uses, affecting a \$3 billion market (Garnett K. et al., 2021). The PEC then formed the basis of the Montreal Protocol in 1987, which we examine in detail in the next section. To date, none of the European legislation in force (apart from transposition of the Montreal Protocol) includes a definition of essential uses, although some of it uses similar methodologies.

4.1 The Montreal Protocol

The Montreal Protocol is an international agreement aimed at protecting the stratospheric ozone layer by eliminating the chemicals responsible for its destruction. It was signed in 1987 and came into force in 1989¹¹ . It was subsequently transposed into European law¹² . It is the regulation explicitly based on essential uses that is most often cited as a model (WSP, 2023).

Here are the key elements.

¹⁰ See this awareness-raising campaign by the NGO ChemSec: <https://chemsec.org/are-you-climbing-mount-everest-or-just-going-to-work/>

¹¹ <https://ozone.unep.org>

¹² Regulation (EC) No 1005/2009

1. Hazardous effects

Destruction of the stratospheric ozone layer.

2. Health and environmental impacts, and the socio-economic damage involved

Overexposure of biota to UV rays, a pandemic of skin cancers and eyesight problems, massive losses in agricultural production, climate change, etc.

3. Targeted substances

Around a hundred synthetic molecules releasing halogenated compounds: chlorofluorocarbons (CFCs), halons and methyl bromide, collectively known as Ozone Destroying Compounds (ODCs).

4. Essential and non-essential uses

Essential uses are defined in the Protocol as those that are necessary for health and safety, and essential for the proper functioning of society (including cultural and intellectual aspects) .^{13,14}

Uses deemed essential are defined in advance of a substitution process, on a case-by-case and country-by-country basis, with a progressive withdrawal schedule. Essential uses include laboratory reagents, rocket engines, torpedo maintenance, aerosols for the treatment of burns, metered dose inhalers for the treatment of asthma and fire-fighting products. Note that the exemption of methyl bromide in agriculture for the preservation of cut flowers and vegetables is based on "critical use".

Uses deemed "non-essential" are prohibited. However, we have not identified any non-essential uses that have been discontinued due to the lack of an alternative solution. It would therefore appear that alternative solutions have been found. Among the uses deemed essential for which substitutions have made it possible to restrict the use of ODCs, while preserving the "essential" service they provide, we find refrigeration systems, fire-fighting agents, inhalation sprays, industrial cleaning agents and insulators. Under the Protocol, the substitution process may be accompanied by aids and constraints. For example, in the case of inhalers, doctors and patients have been familiarised with other types of treatment and forced to make efforts to eliminate or recover the substances emitted when the devices are recharged.

5. Economically acceptable reduction measures for essential uses maintained

The protocol provides for the "Technical and Economic Assessment Panel" (TEAP) to make recommendations on alternatives and replacement products, taking into account the absorption capacity of the environment, health impacts, economic possibilities, availability and regulations. Authorised quantities are set by product, period and country. It should be noted that the EUC is accompanied by an impact assessment and takes account of socio-economic constraints.

6. Assessment of residual risks after implementation of the regulations

Between 1993 and 2020, emissions of chlorine and total bromine (including from natural sources) were reduced by 11% and 15% respectively. According to projections, this reduction should continue steadily until 2100. Restoration of the ozone layer should be complete by 2066, returning to 1980 levels. The Protocol is therefore generally regarded as a success, which has contributed to the rapid spread of the CUE.

As far as implementation is concerned, there is international consensus, with unanimous or near-unanimous ratification of the Montreal Protocol and associated protocols. We have not identified any studies that mention major disruptions to the functioning of society linked to the substitution of CDOs. Positive effects have also been observed, such as substitution by more efficient products in refrigeration systems. It would appear that the Montreal Protocol succeeds in achieving the objective of preserving the ozone layer by negotiating reductions in use without having to give up uses, whether essential or not.

However, a critical analysis of the Montreal Protocol shows that its success was due to the ease with which the industry introduced substitution for CFCs, and also to the fact that the alternatives were perhaps adopted without the in-depth analysis they would have deserved. It turned out that some of the

¹³ Article 2 of the protocol and protocol manual 13^{ème} 2019 edition

¹⁴ Decision IV/25 of the Montreal Protocol

substitutes were powerful greenhouse gases. As a result, the Montreal Protocol had to be supplemented by the Kigali Protocol in 2016. While what appears to be a case of "regrettable substitution" cannot be attributed to the EUC, it does raise questions about the link between the EUC and the lack of attention and effort on a consequential risk/benefit analysis of substitution. It should also be noted that, despite the EUC, the use of methyl bromide has continued to be authorised for agricultural applications, under pressure from industry and due to scientific uncertainties (Gareau B.J., 2010). In addition, the suggestion made at the 4th meeting of the Parties to the Protocol in 1992 to exclude uses in luxury goods went unheeded. Stakeholders preferred to carry out a substance-by-substance risk analysis for these uses, on a case-by-case basis, rather than a general restriction based on the essentiality or otherwise of this sector (Garnett K. et al., 2021).

The success of the EUC in the Montreal Protocol must therefore be put into perspective and analysed with hindsight before it can be considered as a transferable model, given that it has been relatively little used and sometimes circumvented in practice.

4.2 The UN Stockholm Convention and the POPs Regulation

The aim of the Stockholm Convention is to protect human health and the environment from persistent organic pollutants (POPs), on the grounds that they possess toxic properties, resist degradation, accumulate in living organisms and are spread by air, water and migratory species across international borders and deposited far from their site of origin, where they accumulate in terrestrial and aquatic ecosystems.

The Conference of the Parties (the States) takes the decision to include a substance on the list of restrictions or bans, on the basis of a proposal from the Parties. The Conference bases its decision on the data provided in Annex D (persistent, bioaccumulative, toxicity and ecotoxicity characteristics), Annex E (exposure and exposure-related risks) and Annex F on the socio-economic considerations of possible regulatory measures (technical effectiveness and costs, substitution possibilities, impact on society, waste, information, control and monitoring).

The positive and negative impacts on society concern :

- ✓ Health (including public, environmental and occupational health) ;
- ✓ Agriculture, aquaculture and forestry ;
- ✓ Biodiversity ;
- ✓ Economic aspects ;
- ✓ The move towards sustainable development ;
- ✓ Social costs.

The EU POPs Regulation¹⁵ translates the commitments of the Stockholm Convention into European law. The Commission may propose that a POP substance be included in the Convention. Exemptions to the restriction may be proposed in the case of an "essential function in a specific application", without giving any further details on the concepts of "essential" and "specific" function¹⁶ .

The POP regulation applicable in France restricts the use of PFAS, including PFOS and PFOA .¹⁷

4.3 The REACH regulation

The REACH regulation considers the hazards of a substance and, depending on the hazards assessed, may restrict or authorise its uses on a case-by-case basis. Hazards are assessed by toxicity and ecotoxicity tests, and certain hazardous substances are then subject to risk reduction measures, through authorisations or restrictions .¹⁸

Applications for authorisation are made by the manufacturers or users of the substances. The restriction procedure is implemented at the request of Member States to prohibit certain uses of substances that are deemed to present risks. Exemptions to the restriction may be included in the "restriction dossiers".

¹⁵ Regulation (EU) 2019/1021 of the European Parliament and of the Council on persistent organic pollutants

¹⁶ Recital 7 of the above-mentioned regulation 2019/1021

¹⁷ PFOS: perfluorooctane sulphonic acid. PFOA: perfluorooctanoic acid.

¹⁸ REGULATION (EC) No 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 18 December 2006, Annexes VII to X

To decide on authorisations or restrictions, REACH provides for Socio-Economic Analyses (SEAs)¹⁹ and Analyses of Alternatives analysed by SEAC²⁰. The authorisation of a substance of very high concern whose risks are not "adequately controlled" or the restriction of a substance can only be granted when it is demonstrated that the socio-economic benefits outweigh the risks. Cost-benefit analysis (CBA) is frequently used for this purpose.

As discussed in the literature review, CBA is a fundamentally different approach from the EUC. However, the EUC has sometimes been used implicitly in certain applications of the REACH regulation. For example, in recent restrictions on certain perfluorinated substances (PFOA, PFAS in fire-fighting foams), exemptions have been granted for uses designated as critical to safety or public health.

Similarly, in a retrospective study on references to essential uses in applications for authorisation or exemption from REACH restrictions, the ZeroPM project notes that for a few authorisation applications, the European Commission did not grant authorisation for part of the requested use when "the specified key functionality is not necessary for the use"²¹, which refers to the first stage of application of the EUC (see the presentation of the EUC as proposed by the European Commission in the following chapter). However, these cases are exceptional. Figuière and co-authors (Figuière D. et al., 2023) believe that there is no need to amend the REACH Regulation to implement the EUC, as the information requested in an authorisation application would be sufficient for this purpose. According to the authors, the guide on socio-economic analysis could be amended to take better account of the EUC, which amounts to recommending a combination of CBA and EUC, a discussion to which this report will return later.

4.4 Plant health regulations

Article 4.7 of the plant health regulation²² stipulates that "if an active substance is necessary to control a serious plant health hazard which cannot be controlled by other available means, including non-chemical methods, that active substance may be approved for a limited period necessary to control that serious hazard". Thus, the use of a substance to control a "serious plant health hazard" could correspond to "an essential use". The text does not specify how it can be assessed and when the level of seriousness justifies the derogation, but refers, without giving any further conceptual details, to the term "necessity". The text seems to link this necessity to the unavailability of alternatives, including non-chemical alternatives, rather than to a gradation or assessment of the "phytosanitary hazard", as confirmed by the examination of the recent text concerning the non-renewal of the Marketing Authorisation (MA) for dimethomorph (EC, 2024).

4.5 The Biocide Regulation

EU Regulation 528/2012²³ on biocidal products authorises derogations from the ban on hazardous active substances. Article 5(2) of this regulation gives derogation criteria similar to some of those in the EUC, in particular:

- ✓ If the substance is "essential" to prevent and control "serious risks" to human health and the environment.

This criterion, which could be described as essential, is accompanied by assessment criteria that are closer to an analysis of alternatives and a traditional "risk/benefit" approach. A derogation can therefore only be granted in the following cases:

- ✓ If non-approval of the active substance could have disproportionately negative consequences for society in relation to the risks ;
- ✓ If the availability of substitute substances has been examined ;
- ✓ And if the derogations are accompanied by risk mitigation measures.

A systematic study would be needed to reach a general conclusion on how these criteria are implemented in the Biocide Regulation, but it may be noted that the arguments used by the EC to renew

¹⁹ Ibid. Annex XVI

²⁰ Socio-Economic Analysis Committee

²¹ <https://zeropm.eu/>

²² EP and Council Reg. 1107/2009 concerning the placing of plant protection products on the market .

²³ Case presented in the communication (2024) 1995 op. cit.

the authorisation of propiconazole (EC, 2023) focused on these last assessment elements without seeking to assess the "indispensable" nature of the use in any other way.

Article 37 also allows Member States to grant derogations from marketing authorisations for biocidal products, on the basis of criteria similar to those proposed for the EUC. These are "grounds relating to:

- a) environmental protection ;
- b) public order or public safety ;
- c) the protection of human health and life, particularly of vulnerable population groups, as well as animal and plant health and life ;
- d) the protection of elements of the national heritage of artistic, historical or archaeological value;
- e) target organisms not present in harmful quantities.

The criteria here are fairly precise and only partially overlap with those in the European Commission's proposals for the EUC.

Conversely, a Member State may authorise a biocidal product containing a non-approved substance, but here only one criterion is explained (Article 55-3) for cultural heritage alone: "the said active substance is essential for the protection of cultural heritage and no valid alternative solution exists". Article 56-1 adds to this criterion cases of use for research and development.

5 The European Commission's April 2024 proposal

WSP has carried out a study on behalf of the European Commission's DG Environment (WSP, 2023) as part of the preparation of the Commission's communication on essential uses of 22 April 2024, which is based on the definition in the Montreal Protocol. This study compares four ways of implementing essential uses in relation to the REACH regulation: A) Optional use to extend authorisations or exemptions; B) Optional opposable uses to limit or extend uses; C) Introduction of the method as a complement to or substitute for socio-economic analysis and risk assessment; D) Use of the method as a replacement for socio-economic analysis and risk assessment. A comparative analysis of the 4 options shows that option D would be the most protective for health and the environment, but with the greatest economic and social impact, except for administrative costs, which would be reduced.

WSP also carried out a consultation during workshops, which led to the emergence of a number of significant stakeholder positions. For example, the European Chemical Industry Council (CEFIC) proposed introducing the EUC into the REACH regulation by making it a ground for exemption from restriction or a ground for authorisation additional to those of a CBA, which would make the regulation more flexible²⁴. For the NGO ClientEarth (ClientEarth, 2024), the EUC can either speed up or have no effect, or even slow down the withdrawal of hazardous substances, depending on how it is implemented in the regulations. The NGO stresses the latitude of communication on the criteria for acceptable alternatives or on the hazard criteria adopted. It recommends lowering the performance requirements for alternatives, strengthening the criteria for socio-economic analyses, and structuring the essentiality criteria.

Following WSP's preparatory work, Commission Communication C/2024/2894 was published in April 2024²⁵. Its aim is to provide criteria and guidance for the implementation of the EUCP. The Communication states that the purpose of the EUC is to improve the protection of health and the environment. It sets out the Commission's dilemma, which is that it wants to see the development of "green" technologies and the digital transition, but stresses that these technologies may use hazardous molecules that would otherwise have to be eliminated. The concept of essential uses makes it possible to assess whether it is justified, from a societal point of view, to use the most harmful substances. In cases where the use is necessary for health and/or safety and/or if it is essential for the functioning of society, and if there are no acceptable alternatives, the substance may continue to be used for this

²⁴ <https://cefic.org/app/uploads/2021/05/2021-05-How-to-introduce-the-%E2%80%98Essential-Uses-Concept-under-REACH-Concept-paper.pdf>

²⁵ 22.4.2024 C(2024) 1995 final op. cit.

purpose for a certain period of time. It adds that the concept of essential use is designed to help industry by facilitating exemptions from restrictions.

According to the communication, there are currently no plans to introduce the EUC in a European regulation. Nor will the technical and economic assessment criteria included in the regulations be modified. Nevertheless, the document anticipates what could be introduced into legislation and how to implement the EUC, taking into account the specific features of the different legislations. The Commission proposes two levels of implementation of the EUC : as a complement to existing regulations, and through voluntary action, in particular by "proactive" companies seeking to reduce their impacts.

5.1 Description of the stages and key elements of the EC proposal

5.1.1 Implementation stages

The communication details the stages of the EUC:

Stage 1 - Description of the uses of the substance and associated uses.

- ✓ Is the substance necessary to satisfy the use? The EC recommends using the use descriptors proposed by ECHA as part of REACH²⁶ ;
- ✓ The use must be described in terms of its ability to satisfy a need in a product or service;
- ✓ The description of the use must enable an analysis of the alternatives in terms of their ability to satisfy the need;
- ✓ Scenarios of exposure to the substance during its use must be described in order to assess the risks of alternatives.

Stage 2 - Assessment of the essential nature of the use (or the service provided to society)

- ✓ If the function of the substance is not necessary to fulfil the use, its use is not essential;
- ✓ If the use is not critical to health, the environment or the functioning of society, it is not essential;
- ✓ The EUC dispenses with the need to seek out or evaluate alternatives if the need is not deemed essential;
- ✓ If a satisfactory alternative is known, there is no need to consider whether the service provided is essential. It must be implemented.

Stage 3 - Evaluation of alternatives

- ✓ Acceptable alternatives according to the communication are those that provide functions with performance acceptable to society in order to satisfy its needs, even with reduced performance;
- ✓ The notion of "acceptable alternative" is normally defined by specific requirements in each legislative text and, for most of them, it also includes an assessment of technical and/or economic feasibility. Existing definitions (e.g. technical and/or economic feasibility) should be taken into account when implementing the concept of essential uses in regulations (notably REACH).

5.1.2 The hazards of substances covered by the EUC

The hazards of substances that require them to be examined through the prism of the EUC are defined in a positive list, based on the criteria in the REACH regulation. :

- Carcinogenicity Cat. 1A and 1B ;
- Germ cell mutagenicity Cat. 1A and 1B ;
- Reproductive/developmental toxicity Cat. 1A and 1B ;
- Endocrine disruption Cat. 1 (human health) ;
- Endocrine disruption Cat. 1 (environment) ;
- Respiratory sensitisation Cat. 1 ;

²⁶ Appendix R.12.4. of the Guidance on Information Requirements and Chemical Safety Assessment Chapter R.12: Use description Version 3.0 - December 2015

- Specific target organ toxicity - repeated exposure (STOT-RE) Cat. 1, including immunotoxicity and neurotoxicity ;
- Persistent, bioaccumulative and toxic/very persistent and very bioaccumulative (PBT/vPvB) ;
- Persistent, mobile and toxic/very persistent and mobile (PMT/vPvM) ;
- Hazardous for the ozone layer.

5.1.3 Essential services to be maintained

Here are the elements selected by the EC. They are described in the annex to the communication and summarised here:

- a) Actions required for health or safety :
 - Prevent, monitor or treat illnesses and similar health problems;
 - Maintain basic conditions for human and animal life and health;
 - Managing health crises and emergencies;
 - Ensuring personal safety ;
 - Ensuring public safety.
- b) Critical for the functioning of society : :
 - Providing resources or services that must remain in service for society to function. The services in question are energy storage and supply, transport, water and waste treatment, digital communications and healthcare infrastructures, essential digital services, critical raw materials and essential measurement and testing systems. More generally, these are services whose failure or degradation would lead to significant disruption of public safety and security, or other dramatic consequences;
 - Managing societal risks and the impact of crises and natural disasters;
 - Protecting and restoring the natural environment ;
 - Carry out scientific research and development;
 - Protecting cultural heritage.

The EC specifies that "properties related to convenience, leisure, decoration²⁷ or luxury" are "normally" considered to be non-essential as they do not fall into the above categories.

The Annex provides important clarifications, but it is not without its difficulties, as many terms such as "in particular" (used almost systematically before describing the essential uses in concrete terms) or "significant" refer to the difficulty of establishing limits and thresholds. The definition is recursive on several occasions: the terms "critical" and "necessary" (which are not defined²⁸) themselves appear in the text of the definition, which is supposed to make them explicit, making their application complex.

For several criteria, e.g. "Treat comparable diseases and health problems", the Commission suggests carrying out a comparative risk analysis (between those linked to PFAS and those linked to the diseases concerned) for PFAS substances that pose a hazard to health or the environment. Such an analysis could present methodological difficulties and involve a great deal of analytical work, with high levels of uncertainty, for example to carry out a risk comparison between a biocide that reduces the risk of spreading epidemics and one that poses health or environmental risks. The trial application to PFAS reported later in this report will highlight other difficulties.

²⁷ The decorative function, insofar as it may confer an aesthetic value that is likely to be officially recognised (UNESCO), is however included as one that may be deemed essential, under the heading of "protection of cultural heritage".

²⁸ A glossary could have been useful as an aid to interpreting the EC Communication.

5.2 Discussion of the EC proposal

5.2.1 Hazard criteria

As long as the EUC is implemented within the framework of an existing regulation, the criteria of the regulation logically apply. However, the EUC could also cover hazards that are not currently covered by an existing regulation (either by amending that regulation or by a new specific regulation). In any case, defining the hazards "eligible" for the EUC is a decisive step in determining the potential impact of its application.

Although not part of the EUC, the grouping of structurally related substances for a common treatment of risk management procedures is closely associated with it. The way in which groups are set up is a fundamental issue in the process, as it can simplify the process, reduce costs and decision-making times (Cousins I. et al., 2020), or on the contrary lead to the unnecessary banning of substances that may have uses that are, if not essential, at least beneficial to the functioning of society. Grouping also makes it possible to reduce the risk of regrettable substitution by a substance with a similar structure, fulfilling the same technical function, but for which the hazard assessment is inadequate. The scientific methods used to classify groups of substances (QSAR models, etc.) and the level of scientific evidence deemed necessary to establish a hazard are complex issues that have been widely documented and debated elsewhere, and are outside the scope of this work.

5.2.2 Essentiality criteria

Criteria or case-by-case

Two solutions are a priori possible: either work via a flexible case-by-case assessment based on very generic criteria, or via a highly structured assessment based on very precisely developed criteria. Intermediary approaches are conceivable: for example, starting to implement the EUC on a case-by-case basis for the first cases, which would enable more elaborate criteria to be developed progressively, with this increase in complexity being based on experience gained.

The EC proposal opts for a fairly elaborate criteria-based approach, the definition of which is significantly more precise than in the Montreal Protocol. It gives a long list of uses to be considered, which is a priori the most complete working basis to have been published to date.

Improving and co-constructing criteria

These criteria are the result of work carried out by a consultant (WSP), who organised workshops with stakeholders, and then work by the European Commission on this basis. They have therefore not been developed collectively by society, which, when it comes to prioritising human activities, could be a handicap in terms of legitimacy. As a result, it could be useful to carry out a co-construction exercise to validate or modify this initial proposal. One difficulty inherent in such a construction is the variability of essentiality according to culture, social position, etc., which is therefore both spatial and temporal (Sulfill A. et al., 2024). The question of leisure, luxury, etc., which is dealt with in the EC proposal, is probably more complex in terms of knowledge and perceptions by society²⁹. Consistencies may also appear, for example in a sociological survey carried out in various European countries, it appeared that health or safety products are generally perceived as more essential than cosmetic products (Karinen, A. K., 2024).

As we have seen, a number of social science researchers who have studied the EUC suggest that democratic processes should be used, possibly with innovative procedures, to try to arrive at acceptable and legitimate definitions. Pure decision-making assistance from "experts" (for example, who would draw up detailed guides, according to other proposals) could raise questions about the definition and recognition of their competence and legitimacy. Conversely, it is likely that when citizens are questioned about essentiality, their "lay" perception of chemical risks will come into play. (Sulfill A. et al., 2024) suggests using behavioural sciences to clarify and control the influence of these dimensions in discussions with citizens.

Finally, reflecting these difficulties, we had already noted the very frequent presence of qualitative terms such as "necessary", "essential" or "particularly" in the definitions, which are therefore mostly recursive. Testing and increasing the levels of consensus, while trying to specify the essential uses, and reducing

²⁹ See for example (Cristini H. et al., 2017) on the different ways of conceiving and perceiving luxury, or (Fancourt D. et al., 2021) on the health benefits of leisure.

the presence of terms that generate uncertainty could be the objective of work that would involve the collective construction of more complete descriptions.

5.2.3 Analysis of alternatives

In the EC scheme, the decision on essentiality is closely linked to an analysis of the feasibility of alternatives. This point merits attention, as the difficulties of analysing alternatives are one of the main causes and aspects of the recent plans to reform the REACH regulation. The EC's communication on the EUC says little about whether risk/benefit (or cost/benefit or "socio-economic") assessments should be carried out when assessing essentiality. This is because the implementation of the EUC will often involve the implicit or explicit resolution of management conflicts between the risks associated with the loss of a service or function for society and those associated with the intrinsic hazards of the chemical. The question may be to decide to what extent a function is "indispensable" given the risks of the chemical. This is also an important point, which we have seen gives rise to contrasting views among stakeholders.

Whether or not to include "analyses of alternatives" and/or "socio-economic analyses" in the PEC is a highly structuring choice. Broadly speaking, the advantages and disadvantages of the two options are as follows:

- Failure to take account of the availability of alternatives and the socio-economic consequences, for example of "non-essential" use, may initially make decisions simpler and quicker, but may generate obstacles, resistance to its application, or disputes if socio-economic difficulties are experienced by certain stakeholders that have not been anticipated;
- Linking the two subjects systematically amounts to adding a concept of "essentiality" whose added value is not clear, if in any case the alternative and socio-economic assessments already planned will be carried out anyway. It will then be necessary to define how this third element comes into play in decision support and decision-making. In this configuration, essentiality could, for example, be a factor taken into account alongside others in a "qualitative/weight of evidence" approach, such as that recently adopted by ECHA's Socio-Economic Analysis Committee (ECHA, 2022).

The experience acquired under the REACH regulation, and in particular the authorisation procedure, on the analysis of alternatives must be taken into account when deciding how to link them to the EUC.

This experience shows that analysing alternatives is a difficult step in practice, due to problems of access to data and the difficulty of assessing the economic and technical feasibility of alternatives. This step could therefore remain a limiting factor for the implementation of a EUC scheme as proposed by the EC. In more detail, the difficulties encountered in the context of REACH are as follows:

- The industry is the main prescriber of the use of chemical products, in that it evaluates and establishes the technical performance levels that then imply the use of chemical products. It is also the main contributor to the drafting of industrial standards, which are references used directly, or indirectly via safety standards for example, to set the technical constraints resulting in performance requirements for the use of chemical products. So industry is the source and holder of information on the technical performance and costs of alternatives, and it is difficult for public authorities and their experts to go against this "information asymmetry". This situation makes it difficult to know to what extent the required levels of performance are always necessary. In particular, in sectors where supply chains are very complex, it may be preferable for specifiers at the 'upstream' end of the chain (e.g. car manufacturers in this sector) to set uniform performance levels covering all their suppliers on the basis of the most stringent requirements. The complexity of organising the production of end products and the problem of access to information is also a difficulty that can often be encountered by the industry itself. This situation can sometimes constitute a barrier to the knowledge and evaluation of alternatives.
- Consumer needs are invoked to justify the performance levels to be achieved, but these are generally not clearly demonstrated, sometimes in areas that would probably be "non-essential" in the EC classification. In the case of decorative chrome plating, for example, a number of car manufacturers and sanitary appliance manufacturers state in their REACH authorisation applications that consumers have strict aesthetic performance requirements, but do not produce any market studies to back them up. Such studies, especially if the risks associated with

chemical products and alternative solutions were presented to consumers, could perhaps highlight a flexibility in their needs and modify the results of certain assessments of the feasibility of alternatives.

- The analysis of alternatives in REACH has most often been carried out by taking into account only chemical alternatives, without broadening the question to other ways of providing the desired functionality (alternative materials that no longer require chemical treatment, non-chemical treatments and processes, other ways of providing the desired service through the function). The risks of chemical alternatives are not necessarily assessed, and the other environmental aspects of alternatives (chemical or otherwise) are only very rarely taken into account, due to a lack of data and methodological difficulties in making comparisons.
- The above difficulties in assessing technical feasibility have major repercussions on assessing the economic feasibility of alternatives, since in the absence of feasible technical alternatives, or in the face of risks of loss of performance, the manufacturers concerned report market losses or even major risks of closure if the chemical they are currently using were to be banned. Under REACH, the assessment of economic feasibility is carried out, according to ECHA's interpretation and guidelines, from the point of view of the industrial user of the chemical, which has meant that any positive economic effects (development and adoption of an alternative by competitors) are generally not taken into account. Regardless of this practice, taking competitors into account would require detailed knowledge of their economic and market situations, which would be difficult to obtain and evaluate, again because of information asymmetry.

Because of these difficulties and the often significant uncertainties about the technical and economic feasibility of alternatives, variable and potentially significant substitution timescales (up to 12 years or more) are granted under REACH, and in particular under its authorisation procedure. As a result, the modulation of this period has become an instrument for managing uncertainty and even risk: high levels of uncertainty about the possibilities of substitution are reflected in the long periods allowed for substitution, and vice versa.

5.2.4 Socio-economic analysis

With regard to socio-economic analysis, REACH often uses cost-benefit analysis (CBA), which compares the benefits in terms of avoided impacts on human health and the environment with the economic costs of substitution³⁰. CBA, which is widely used in the USA and the UK, and has been introduced into European regulations including REACH, is the subject of controversy (ClientEarth, 2021) which, as the preceding literature review has shown, is at the heart of the EUC discussion, because of its roots in welfare economics and the notion of utility, which is central to classical economic theory (Maxim L., 2023), but which could be opposed to the "essentiality" criterion. The purpose here is not to set out this controversy but to mention certain more practical problems of implementing CBA, which need to be known in order to plan its possible use in connection with the EUC :

- One of the major advantages of CBA is its consequential and global approach, which allows and requires to take an interest, in a logical scheme, in all the positive and negative implications of stopping the use and employment of an alternative to a chemical product: economic effects as a whole, chemical risks of the alternatives, other environmental impacts (energy consumption and CO₂ impacts, water consumption, atmospheric pollution generated, etc.). Apart from the controversy mentioned above, the CBA is therefore a tool that seems capable of helping to assess essentiality in a broader context by systematically examining the consequences of giving up what is deemed "non-essential" on the basis of the EUC. To enable this, decision support in general, and CBA (and chemical risk assessment), will need integrated environmental assessment tools. This could logically lead to the use of Life Cycle Assessment (LCA) to quantify

³⁰ These are not gross financial costs, but the loss of a fraction of the community's limited resources, as a result of their allocation to chemical substitution rather than to other common goals (other environmental health priorities, other government missions, other contributions by private players to the production of added value). In the studies carried out under REACH, because of the difficulty of observing and estimating this loss, the gross financial cost of substitution or the loss of profit of the players most directly involved in substitution is used.

these impacts (Dong Y. et al., 2018). LCA, the benchmark approach for integrated environmental assessment, is a powerful but time- and data-consuming tool. It has limitations in terms of methodology and is subject to its own controversies (Bates-Kassatly V. et al., 2022).

- For chemicals that are persistent, bioaccumulative and toxic (PBTs), or very persistent/bioaccumulative (vPvBs), CBA cannot be applied because the use of PBTs leads to unpredictable exposures over very long periods and their impacts on health and the environment cannot be assessed. In this case, the European Chemicals Agency recommends the use of cost-effectiveness analysis (CEA), which involves calculating ratios between substitution costs and avoided effects (for which avoided emissions or quantities not placed on the market are used as the best available approximation). These ratios expressed in €/kg can then be compared with benchmarks provided by previous similar accepted decisions to help decide on risk management measures.

One of the advantages of CEA over CBA, which makes it interesting for helping to make faster decisions on chemicals more broadly than for PBTs and vPvBs alone, is its simplicity and lower data requirements, as it is not necessary to quantify the impacts on health and the environment (Brignon J.M et al., 2023). This is particularly the case for PFASs, and therefore in their case, implementation of the PEC cannot be based on a CBA, but recourse to the CEA may be considered.

Despite these limitations, economic analysis can be a complementary tool to the EUC and can be used to verify the consequences and therefore to build a consensus around decisions to implement the EUC. It has the major advantage of requiring the construction of a consequential, descriptive and scenario-based vision of decisions on essentiality. But its implementation presupposes that the difficulties in evaluating alternatives, which do not appear to have been satisfactorily resolved to date, are gradually lifted. In addition, REACH's experience in constructing and evaluating economic scenarios shows that it is difficult for experts to assess the competitive situation in a market, the financial situation of companies or the resilience of their value chains, which are the basis of the scenarios.

5.2.5 Decision-making and governance processes

It would seem difficult to implement the EUC without an analysis of alternatives and an analysis that takes into account the socio-economic consequences of banning measures, particularly in order to be able to set deadlines for their implementation. These two tools are already widely used. So the novelty of the EUC could lie not in a change of analytical tool but more in the implementation processes for building consensus around risk management decisions. This would confirm what has emerged from the analysis of the literature on the EUC, i.e. that several authors place the priority not on analytical tools piloted by experts, but on consultation and deliberation bodies and processes that can have a representativeness and legitimacy that experts, decision-makers or stakeholder meetings will not have.

In this context, processes other than those currently used for chemical risk management may need to be created or adapted from other contexts, not only for decision support but also for collective decision-making, with a focus on the notions of equity between social groups and reproducibility of decisions. We do not intend to develop such an analysis, as it would go beyond the scope of this report, and will simply mention that public consultation tools are already used in France (Commission Nationale du Débat Public) and that, from an analytical point of view, decision-support tools such as deliberative multicriteria analysis³¹ could prove interesting, as a replacement for or in combination with those already mentioned. Although mentioned in the ECHA guidelines on "socio-economic analysis", multicriteria analysis has not, to our knowledge, been used to help make decisions on restrictions or authorisations. An example would be a multi-criteria analysis incorporating an essentiality criterion, combined with others concerning the risks avoided, the costs of substitution, etc.

³¹ A brief review of the scientific literature on "participatory multicriteria analysis" or "deliberative multicriteria evaluation" etc. seems to point to numerous applications, particularly in the field of water management or ecosystem services. Water management is characterised by a tradition of structured consultation within river basin bodies, particularly since the creation of the Water Agencies in France. It is beyond the scope of this report to go into this in depth, but a retrospective analysis of the motivations and results of this specificity could provide lessons for a study of a deliberative framework for essential uses.

We will also only touch on the question of how much and under what conditions the EUC would contribute to better implementation of the fundamental principles of environmental law, namely the precautionary principle, the principle of prevention and the polluter pays principle. In the context of the implementation of REACH, these subjects, and in particular the precautionary principle, have been regularly raised, but to our knowledge have been relatively little formalised and studied, and have to do in particular with the balance between management by risk or by hazard (Foss Hansen, S et al., 2007)³². However, it is clear that the treatment of uncertainties and the degree to which precaution is taken into account are heterogeneous within the scientific practices used in the REACH regulation, and in particular between chemical risk assessment (which systematically introduces precaution in its treatment of uncertainties) and socio-economic assessment (which, on the other hand, provides generally median estimates for its economic aspects), cf. (Péry A. et al., 2013).

5.2.6 Objective for risks reduction

In cases where alternatives are not immediately or totally available, the objective for reducing risks, emissions or exposures could be decisive in the implementation of the PEC. In general, the higher the risk reduction ambitions, the higher the corresponding costs, and discussion of the acceptability of the costs may require the risk reductions achieved to be explained and how they compare with the targets³³. Setting and communicating risk reduction targets that are consistent between chemicals and types of risk would therefore seem to help at these stages of the decision-making process, but it is an approach that presents methodological, scientific and sociological difficulties.

6 Application of the concept of essential uses proposed by the EC to PFAS

In this final part of the report, we look at the sectors in which PFAS are used, in order to produce a purely illustrative simulation³⁴ of what the application of the essential uses criteria, as proposed by the EC, could lead to.

6.1 Illustrative analysis by type of use

In the context of this report, we cannot deal systematically and more than superficially with the availability of alternatives and the socio-economic consequences of discontinuing use, and so they will not be taken into account in this analysis, which we wish to focus on the essentiality criteria. We are basing our analysis on the structuring of uses, on the data and assessments carried out as part of the investigation into the proposal for a "universal" restriction on PFASs under REACH, and on a recent study by Ineris listing uses and substitution possibilities (Ineris, 2024). The sectors will be treated in a non-exhaustive and aggregated manner, as hundreds of applications and dozens of different technical functions are concerned. We present this analysis, which is therefore very simplified, in the form of a table comparing these uses with the corresponding essentiality criteria. We favour a close textual analysis of the CUE criteria in the "applicable essentiality criteria" column, and then mention possible difficulties or possibilities of interpretation in the "Comments" column.

³² In the context of possible revisions to the REACH regulation, the EC has commissioned a study on the possible extension of hazard-based management, making it more systematic and for more hazard classes, see https://single-market-economy.ec.europa.eu/system/files/2022-06/REACH_Workshop%20report%20_21_03_2021.pdf.

³³ The EC text proposing the EUC states, without further elaboration, that "the use concerned by a derogation shall be subject to appropriate risk mitigation measures in order to reduce to a minimum the exposure of humans, animals and the environment". The objective of risk minimisation is already present in the current regulations, but is rarely or never made explicit.

³⁴ Among other reasons, it is the result of the personal reflections of Ineris experts, whose legitimacy and knowledge are very limited in relation to the complexity of PFAS uses, and without any deliberative or consultative process.

Table 1. Illustrative example of the application of the essential use criteria proposed by the European Commission to PFASs

| Sector | Uses | PFAS function | Applicable essentiality criteria ³⁵ | Comments |
|------------------|--|--|---|----------|
| Textile industry | Consumer clothing | Water-repellent, Oil-repellent, Resistance to stains and dirt | | |
| | Protective clothing for professionals | | "Ensuring the operation of personal safety equipment" | |
| | Furnishing fabrics | | | |
| | Textile treatments by private individuals (sprays) | | | |
| | Leather | | | |
| | Textiles for motor insulation | Sound and vibration insulation | "Ensuring the safety of products, equipment and tools And/or "Enabling the installation, maintenance and transport of infrastructure and services essential to society, such as [...] mobility and transport (e.g. road ..." | |
| | Technical textiles (membranes, etc.) | Filtration, purification, disinfection in various industries (drinking water, food processing) | "To enable the installation, maintenance and transport of infrastructure and services that are essential to society, such as [...] water treatment and supply". "Guarantee the availability of foodstuffs [...] through production uses". "Guaranteeing clean water in sufficient quantities" | |

³⁵ According to Tables 2 and 3 of the EC Communication. **Legend:** red if no essentiality criterion seems to us to apply indisputably, green otherwise, with mention of the essentiality criterion that may apply.

| Sector | Uses | PFAS function | Applicable essentiality criteria ³⁵ | Comments |
|--------------|--|---|--|---|
| Food contact | Coatings for paper and cardboard food packaging | Barrier against grease and water | | Appears to involve takeaway food, |
| | Coatings for plastic food packaging | Processing aids for polymers used in the extrusion of flexible plastic films (these polymers enable faster, more energy-efficient production). Improving hydrophobic qualities Reinforced packaging | "Guaranteeing the availability of food and foodstuffs [...], through uses in [...] storage, distribution". | If the 'hydrophobic' function of PFASs plays a role in terms of the hygiene of packaged foods, this function could also be linked to the prevention of communicable diseases and the availability of food. Further data and evaluation would be required. |
| | Other coatings for packaging (outside of cans, etc.) | Improving productivity Cleanliness/hygiene (stain/fouling prevention, etc.) | "To guarantee the availability of food and foodstuffs [...], through uses in [...] storage, distribution". | |
| | Non-stick coating for domestic kitchen utensils | Non-stick Durability | | |
| | Non-stick coating for professional kitchen utensils and in the food industry | Non-stick Durability | | |
| | Equipment in the food industry (valves, conveyor belts, etc.) | Non-stick Productivity Hygiene | "Guarantee the availability of foodstuffs [...] through production uses". | Similar uses throughout industry, e.g. <i>valves, seals, pipe linings, etc.</i> |
| Construction | Anti-stain treatments for glass and ceramic surfaces (windows, mirrors, shower doors, baths and toilets) | Anti-dirt | | |
| | Fluoropolymer films and sheets for greenhouses | Self-cleaning, durability | "Guarantee the availability of foodstuffs [...] through production uses". | |
| | Frames and films for PVC windows | Durability: protection against chemicals, corrosion, weathering and UV rays | | |
| | Paints and coatings, fabrics and membranes for the construction industry | Durability: protection against chemicals, corrosion, weathering and UV. | | It is conceivable that the function could in some cases be to protect cultural heritage, which could lead to the classification shown opposite being revised in this case. |

| Sector | Uses | PFAS function | Applicable essentiality criteria ³⁵ | Comments |
|----------------------|--|---|---|--|
| | Asphalt roofs, metal roof coverings, waterproofing membranes for flat roofs | Durability: protection against chemicals, corrosion, weathering and UV. | "Guaranteeing warmth, shelter and protection from the environment" | |
| | Support devices for bridges and buildings | Management of expansion of structures, anti-seismic protection | <p>"Ensure the safety of infrastructures, such as road, rail and air safety and the safety of buildings".</p> <p>Or</p> <p>"To enable the installation of [...] infrastructure [...] that is essential for society, such as [...] mobility and transport (e.g. road, rail...)".</p> | Although the parenthesis specifying the safety situations does not provide for this case: "(use in lifts, fire alarms and fire-fighting equipment)". |
| | Joints and adhesives for the building and civil engineering industry (pipes, etc.) | Heat and water resistance | <p>"To enable the installation, maintenance [...] of infrastructure and services essential to society, such as [...] the supply of energy [...] (oil, gas), water treatment and water supply".</p> <p>"Guaranteeing clean water in sufficient quantities"</p> | |
| Fire fighting | Fire-fighting foams | Surfactant: film-forming capacity, fuel repellency and high ambient temperature performance | "Ensure the operation of emergency services, including ambulance and fire services." | |

| Sector | Uses | PFAS function | Applicable essentiality criteria ³⁵ | Comments |
|---------------------|--|---|--|---|
| Electrical industry | Wires and cables | Combination of high performance levels in terms of : High thermal stability, non-flammability and high melting point. Inertness to chemical attack. Permeation. Low coefficient of friction. Electrical properties. | <p>"To enable the manufacture, supply, maintenance and recycling of essential equipment and components for resources and services that are essential to society".</p> <p>Or</p> <p>"To ensure the safety of products... which may be heated to a temperature where they could ignite.</p> | A note specifies that semiconductors are expressly covered by this wording. |
| | Electronic components | | | |
| | Semiconductors | | | |
| Energy | Films in photovoltaic cells and solar panels | UV, heat and chemical resistance | <p>"Enable the installation, maintenance [...] of infrastructure and services that are essential to society, such as the conversion, storage and supply of energy (e.g. renewable energies, electricity...)".</p> <p>"Ensure the corrosion protection of products used in environments where this is necessary".</p> | Note the apparently recursive nature of the definition, which would therefore require us to examine whether the fields of application themselves fall into one of the categories of the definition. |
| | Protection of wind turbine blades | Durability: protection against chemicals, corrosion, weathering and UV rays | | |
| | Membranes, diaphragms, seals, etc. in electrolysers, fuel cells and batteries. | Functional parts/components of the energy production/storage device, with corrosion, chemical and temperature resistance performance. | | |
| Lubricants | Lubrication of parts (bearings, jacks, screws, nuts, etc.) in a wide range of sectors: food, aeronautics, automotive, rail, nuclear, electronics, medical, renewable energies, oil and gas, etc. | Optimisation of production processes or product use (cost, energy consumption) | | Other cases than vehicle brakes would seem to pose comparable safety issues (shock absorbers, landing gear, etc.). |
| | | Lubrication of parts whose correct operation is important for safety | "Ensuring the safety of products, equipment and tools by lubricating vehicle brakes". | |
| Heat transfer | Refrigeration, air conditioning and heat pump systems | Cooling or heating function (for heat pumps) | <p>"Guarantee heat [...] against the surrounding environment.</p> <p>or</p> <p>To enable the installation, maintenance and transport of infrastructure and services that are essential to society,</p> | <p>The air conditioning of homes or communal areas is not one of the "basic needs". It should be noted, however, that the list of basic needs is preceded by "in particular".</p> <p>Although not explicitly stated, it could also cover the air-conditioning needs of these essential infrastructures.</p> |

| Sector | Uses | PFAS function | Applicable essentiality criteria ³⁵ | Comments |
|---|--|--|---|--|
| Metallisation and manufacture of metal products | <i>Hard</i> chromium plating baths for various industries (automotive, aviation, printing, etc.) | Anti-corrosion protection, anti-chemical aggression, friction reduction | "Ensure the corrosion protection of products used in environments where this is necessary". | The context of the uses seems to correspond to the need mentioned, which can be assessed through the other criteria. However, the case of the printing works does not seem essential according to the criteria of the EUC given by the EC. |
| | <i>Decorative</i> chrome plating baths (automotive, sanitary, perfumery, etc.) | Aesthetics and protection against corrosion and chemical attack (durability) | | In "Ensuring the [...] corrosion protection of products used in environments where this is necessary", the context and function of decorative uses do not seem to correspond to the need mentioned, which can be assessed through the other criteria of the EUC given by the EC. |
| Mining industry | Wetting agents for ore leaching | See description of use | "Enabling the extraction, processing, recycling and storage of critical raw materials ³⁶ | It remains to be demonstrated that the wetting agents provide an essential function for the use shown opposite. |
| Oil industry | Anti-foaming agents for drilling fluids Plotters for mapping oil and gas reserves | See description of use | Enabling the installation, maintenance [...] of services essential to society, such as the conversion, storage and supply of energy (e.g. [...] oil, gas) | Clarification is needed as to whether oil and gas extraction is included in the definition opposite. |
| Automotive industry Aerospace industry | Hydraulic fluids | Anti-erosion and anti-corrosion additives | "To enable the installation of [...], infrastructure [...] essential to society, such as [...] mobility and transport (e.g. road, [...], air, ...)". | |
| Medical sector | Wicks and wound treatment | Care | "Providing healthcare" | |
| | Tubes and Catheters | Care | | |
| | Metered-dose inhalers (surface treatment and propellants) | Care | | |
| | Sterilising gases | Medical and hospital hygiene | "Guaranteeing hygiene and cleaning in hospitals and similar environments and situations where a high level of disinfection is required". | |
| | Laboratory diagnostics | Medical and biological analyses | | |

³⁶ The criteria refer to a proposal for an EU regulation made by the EC, which contains a proposed list of critical minerals.

| Sector | Uses | PFAS function | Applicable essentiality criteria ³⁵ | Comments |
|--|---|---|---|--|
| | Certain contact lenses and ophthalmic lenses | Ophthalmology | "Treating comparable diseases and health problems". | |
| Valves, seals, pipe linings,... | All sectors (industry, construction, networks, etc.) transporting fluids under conditions that make PFAS functions useful | Production process optimisation / Health and safety functions | "Providing resources or services that must remain available to society". "Provide resources such as infrastructure and equipment to ensure the defence and security of society". | This type of equipment is so widespread that other criteria, if not all the essential use criteria, are likely to apply. |
| Sport | Ski waxing | Sports performance | | |
| Cosmetics | Cosmetic ingredients | Conditioner, swelling agent, detangler, solvent, binder, viscosity control, film-former, surfactant | | |
| | Intermediate for the synthesis of cosmetic ingredients | Synthesis of peptides with anti-ageing, anti-wrinkle, cell rejuvenation and skin barrier function recovery functions. | | |

6.2 Discussion of the results

Taken as a whole, Table 1 seems to show that a small minority of PFAS uses are very clearly "non-essential" (once again, excluding analysis of alternatives and the socio-economic consequences of a ban). However, the criteria do not cover all cases and many of them seem to call for further information, evaluation or debate.

In several cases, the function of PFAS is to ensure the durability of a part or product, which, in the absence of further information on a link with a safety issue, for example, is not admissible in terms of the CUE criteria (although it could possibly be in a "sustainable development" approach). In the case of decorative chrome plating, it is difficult to comment on the "necessity" of the anti-corrosion function included in the statement of the criterion, given that it is clearly part of the aesthetic function, but less clearly in terms of "safety".

In several cases, the PFAS function operates in a sector that provides services that are clearly essential uses, but it is difficult to know, without technical details, to what extent this PFAS function is necessary for the operation of the "essential" sector in question. For example, it would be important to estimate the extent to which wetting agents for ore leaching are necessary for ore production, in order to assess the essential nature of PFAS in this context. It should be noted that descriptions of the "essential uses" of chemicals tend to describe essential services and therefore do not focus on the technical functions of chemicals. It is therefore likely that it will often be necessary to assess whether a chemical product's function is required to provide an essential service.

Finally, it should be noted that for almost all the cases of "non-essential" uses according to the EC criteria listed in Table 1, the current assessment of the Restriction Dossier under REACH also concludes (at the time of writing this report) that a derogation from the proposed restriction would not be justified, without using the EUC, but on the basis of an analysis of the alternatives and the socio-economic consequences of a ban, indicating in particular its degree of "proportionality". This could be taken as an indication that either the EUC is implicitly present in this assessment³⁷ or that the existing tools (analysis of alternatives and socio-economic analysis) lead to very similar results in the case of PFASs. Another hypothesis would be that, for the most hazardous and "high-profile" chemicals such as PFASs, the industrial players themselves implicitly apply the EUC by anticipating the regulations and seeking acceptable alternatives for cases that they anticipate to be "non-essential" compared to risk. A retrospective analysis of the CUE for a larger number of cases of risk management measures for chemical products would be interesting in this respect.

Whatever the reason, this observation may call into question the practical usefulness of the EUC for PFAS, and even more generally for chemical products. This ties in with the idea that, despite the difficulties that have been pointed out, the stage of analysing alternatives and taking account of the socio-economic consequences could in practice be decisive in the overall scheme for implementing the EUC. However, the EUC could remain a tool providing additional resources for prioritising chemical risk management measures, possibly speeding up their implementation by confirming certain decisions, and a means of increasing their transparency through decision criteria that are clear to all and less technical than those of a socio-economic analysis.

³⁷ The NGO ClientEarth believes that the recent proposal for a universal restriction on PFAS can be seen as inspired by this concept.

7 Conclusion and outlook

This document examined the concept of essential use (EU) in the context of chemical risk management, then focusing specifically on PFASs (per- and polyfluoroalkyl substances). It presented the current regulatory context, the actions underway within the European Union and in France, and an analysis of the scientific and methodological data relating to the concept of essential uses. The report also discussed the steps involved in implementing the concept proposed by the European Commission, with an illustrative application to PFAS uses.

Since 1987, the EUC has formed the basis of the Montreal Protocol on substances that deplete the stratospheric ozone layer, although the literature specifically concerning it is fairly limited and recent. As a result, the scientific and technical, as well as political, ethical and social issues raised by the EUC have received little attention in the context of chemical risks, in favour of the development and operational use of concrete criteria. Recently, the importance of implementing (or even creating) forms of consultation and social construction to seek shared definitions of EUC has emerged.

The criteria proposed by the European Commission in April 2024 are accompanied by descriptions that are much more detailed than those used in Montreal, but which are still largely open to interpretation. In terms of process, the proposal relies heavily on existing expert tools under REACH, alternatives analysis, and, more implicitly, socio-economic or risk/benefit assessment. The analysis of alternatives in REACH has been hampered by problems of access to data, and it has proved difficult to assess the economic and technical feasibility of alternatives. It could therefore remain a limiting factor for the implementation of the EUC as proposed by the EC. Socio-economic analysis, despite methodological difficulties, can be a complementary tool to the EUC, to take into account the consequences of essentiality classifications.

As far as the application to PFASs is concerned, introducing the essentiality criteria proposed by the EC does not seem to substantially alter the proposals (and their ongoing examination by ECHA) made in the context of the REACH "universal" restriction. This could be taken as an indication that either the EUC is already implicitly taken into account by all the players involved in the restriction, or that the analyses of alternatives and socio-economic consequences are the ones driving the conclusions.

Even if this conclusion regarding PFASs could be generalised (which would require a retrospective analysis of other past restrictions under REACH), the EUC could remain a tool providing additional resources for prioritising chemical risk management measures, a possible acceleration of their implementation by supporting certain decisions, and a means of increasing their transparency through decision criteria that are readable by all and less technical than those of a socio-economic analysis.

If it is decided to implement the EUC, a number of suggestions can be made regarding its implementation:

- Pursue studies and research to improve knowledge of this concept, which is still relatively under-researched, in particular through retrospective studies, but also by continuing this work, which is still generic in its application to PFAS (for example, in a high-stakes sector such as energy);
- Work on the procedures and tools for involving stakeholders or citizens in the development and implementation of criteria, going beyond the expert assessment procedures in place under the REACH regulation;
- Study the way in which the EUC can be combined with current expert appraisal tools, for example in a "qualitative/weight of evidence" approach, to move towards more operational tools.

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