The Concept of Essential Use to Regulate Chemicals: Legal Considerations

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The European Commission's chemicals strategy for sustainability contemplates using the concept of "essential use" to regulate the "most harmful chemicals" under REACH and other legislation. This article reviews the possibilities and legal implications of the use of this concept within the current REACH Regulation. Essentially, it may be possible to apply the "essential use" concept under the current legal framework as a qualifier to the socio-economic assessments which are conducted when considering a potential restriction or authorisation under REACH. However, the essential use concept cannot serve to extend the list of substances of very high concern nor to refuse authorisation to substances the risks of which are adequately controlled. It can also not serve to reverse the burden of proof that is on authorities to demonstrate under a REACH restriction that a given substance presents an unacceptable risk. In essence, it is the principle of proportionality that should guide authorities in introducing the essential use concept under REACH, which entails to ensure that any restriction is not more restrictive than necessary to serve the legitimate objectives pursued. For many substances of concern, this principle would not allow outright bans of uses only because they are not strictly necessary for safety, security and the functioning of society, as in the Montreal Protocol. This concept could however serve to streamline and speed up authorisation or exemptions from restrictions for essential and strategic uses of substances. But societal benefits in a much broader sense, also taking into account the quality of life, and the evolution of societal needs, would need to be considered in order to regulate other less strategic uses of chemicals of concern in a proportionate manner.

I. The Concept of Essential Use in the CSS and under Existing EU Regulations

1. The CSS

The European Commission's Chemicals Strategy for Sustainability (CSS)[1] was adopted on 14 October 2020 as a follow up to the European "Green Deal" published in December 2019.[2] The CSS contemplates using the concept of "essential uses" to regulate per- and polyfluoroalkyl substances (PFAS) and the "most harmful chemicals", i.e. to allow their use "where proven essential for society". It further specifies that "(t)he criteria for essential uses of these chemicals will have to be properly defined to ensure coherent application across EU legislation, and will in particular taken into account the needs for achieving the green and digital transition". As will be discussed later in this paper, this is important since the CSS makes a clear link between "essentiality" and these fundamental EU policy objectives.

When referring to PFAS, the CSS provides additional granularity to the essential use concept when specifying that "the very large number of uses of PFAS, including some critical for society (for example medical devices) show that some of their uses can bring high socio-economic benefits. Such bene-

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1 Communication from the Commission of 14 October 2020 (COM(2020) 667), Chemicals Strategy for Sustainability Towards a Toxic-Free Environment (https://ec.europa.eu/environment/pdf/chemicals/2020/10/Strate-gy.pdf)

2 Communication from the Commission of 11 December 2019 (COM(2019) 640), The European Green Deal (https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1588580774040&uri=CELEX%3A52019DC0640)

fits should be compared with the socio-economic costs of the environmental contamination and of the adverse effects on human health. A concept that could be useful in this assessment, with the purpose of reducing emissions, is that of essential uses". Thus the CSS envisages to analyse essentiality as part of, or in connection with, their socio-economic assessment.

On 12 November 2020, the European Commission issued a first document on Essential Uses, a "thought starter" prepared for and presented to CARACAL (the "Caracal Paper 1")[3] which contains some initial considerations and questions designed to launch the discussion on the application of this concept under REACH in CARACAL. That document does not include any specific proposal.

It is striking to note, however, that the CSS does not define what those "most harmful chemicals" are that would justify the use of this concept[4], nor what criteria should be applied and what process should be followed to identify or select them. Similarly, this consideration is absent from the Caracal Paper 1.

2. The Montreal Protocol

As noted in the Caracal Paper 1, the concept of essential uses was first applied under the Montreal Protocol on Substances that Deplete the Ozone Layer (the "Montreal Protocol").[5] The Montreal Protocol is a global agreement agreed in 1987 in order to protect the earth's stratospheric ozone layer by phasing out the chemicals that deplete it. Since the publication of the CSS, the Montreal Protocol is commonly referred to as a forerunner in the development of the concept of essential use in the field of chemicals.

Initially, the essential use exemption was not part of the Montreal Protocol. It was integrated to the Protocol in 1992 through Decision IV/4[6] During their Fourth Meeting, the Parties to the Protocol chose to reconsider the absolute nature of the phasing-out and created an exemption mechanism in article 2 to the Protocol to permit production or consumption of the substances controlled by the Protocol when deemed necessary to satisfy uses agreed by the Parties to be essential.[7]

For the purpose of implementing article 2, the Parties adopted Decision IV/25 on Essential Uses in which they elaborated a dual set of exemption criteria to be met:

– Firstly, (i) that the use is necessary for the health, safety or is critical for the functioning of society (encompassing cultural and intellectual aspects), and (ii) that there are no available technically and economically feasible alternatives or substitutes that are acceptable from the standpoint of environment and health[8][8].
– Secondly, (i) that all economically feasible steps have been taken to minimize the essential use and any associated emission of the controlled substance; and (ii) that the controlled substance is not available in sufficient quantity and quality from existing stocks of banked or recycled controlled substances, also bearing in mind the developing countries' need for controlled substances.[9]

Since the Parties have amended the Protocol to include the essential use exemption, they examine essential-use nominations during each Meetings of the Parties.[10] Those decisions show that a very limited number of sectors have been considered essential in the framework of that Protocol, i.e. medical uses, fire protection, crop protection, laboratory and analytical uses, process agents and aerospace applications.

In its Caracal Paper 1, the Commission was clearly inspired by the Montreal Protocol when defining an essential use as one that is "necessary for health,

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3 European Commission document on "Essential Uses" dated 12 November 2020 (CA/61/2020) presented at the 37th meeting of Competent Authorities for REACH and CLP (CARACAL) on 17-18 November 2020.

4 On Page 10 of the CSS, it is specified that the Commission will "extend the generic approach to risk management to ensure that consumer products (...) do not contain chemicals that cause cancers, gene mutations, affect the reproductive or the endocrine system, or are persistent and bioaccumulative." It also refers in that context of "further harmful chemicals, including those affecting the immune, neurological or respiratory systems and chemicals toxic to a specific organ", but no link is made between this listing and the reference to the "most harmful chemicals" as referred to in the same CSS in connection with the essential use concept.

5 Montreal Protocol on Substances that Deplete the Ozone Layer (1987) (https://ozone.unep.org/treaties/montreal-protocol/montreal-pro-tocol-substances-deplete-ozone-layer)

6 Amendment to the Montreal Protocol on Substances that Deplete the Ozone Layer, Copenhagen, 25 November 1992 (https://treaties.un.org/Pages/ViewDetails.aspx?src=TREATY&mtdsg_no=XXVII-2-c&chapter=27&clang=_en)

7 See Articles 2A 4), 2B 2), 2C 3), 2D 2), 2E 3), 2G, 2H 5), 2I, and 2J 5).

8 Decision IV/25 : Essential uses.

9 Ibid.

10 Handbook for the Montreal Protocol on Substances that Deplete the Ozone Layer. (https://ozone.unep.org/sites/default/files/MP_handbook-eng-lish-2018.pdf)

safety or is critical for functioning of society" and for which "there are no available technical and economically feasible alternatives".[11]

Importantly, the Montreal Protocol addresses a very limited number of substances with undisputed and irreversible environmental impacts, not the universe of substances like REACH, and therefore one would certainly have to be prudent when seeking to extrapolate requirements suitable for substances that deplete the ozone layer to other categories of substances. This refers us back to the unanswered question as to which chemical substances are the "most harmful". Also, as demonstrated below, the essential use concept, as developed in the context of the Montreal Protocol could not be used as such, as part of the socio-economic analysis required under the authorisation and restriction processes of REACH, as this would be contrary to the provisions of the REACH Regulation and to the principle of proportionality.

3. The EU Biocidal Products Regulation

In EU law, the test of essentiality for chemicals is not completely new. Under the Biocidal Product Regulation 528/2012 (the "BPR"), certain active substances cannot be approved under the ordinary procedure if they are classified under the CLP as CMR (carcinogens, mutagens and reproductive toxicants), or having endocrine-disrupting properties or meeting the PBT (persistent, bioaccumulative and toxic) or vPvB (very persistent and very bio-accumulative) criteria[12][12], thus substances that would otherwise qualify as substances of very high concern ("SVHC") under REACH.

Under the BPR, an applicant can benefit from an "essential [use]" exemption, if he can show that the active substance is "essential to prevent or control a serious danger to human health, animal health or the environment" or if he demonstrates that "not approving the active substance would have a disproportionate negative impact on society when compared with the risk to human health, animal health or the environment arising from the use of the substance".

This approach of essential use focuses on the environmental or health benefits for society completed by an alternative balance test[13], thus departing from the broader approach of the Montreal Protocol. In fact, the current text of article 5.2 (b) and (c) of Regulation 528/2012 is the third attempt at defining essential uses of a biocides, showing that the concept as defined in the Montreal Protocol is not universal and that it is a difficult concept to grasp. Its reference to proportionality is however very relevant as discussed below.

To the best of our knowledge, the Commission has issued five decisions under the legal regime applicable before the BPR[14] and eight since then[15]in which it considers this exemption. All of them were granted on the basis of a public health interest.

II. Key Considerations for the Possible Accommodation of the Concept of Essential Use Under Reach and the CLP Regulations

The REACH Regulation is the legal framework that applies today and probably the main target for the introduction of the essential use concept by the European Commission. It is also the legal framework under which a proposed restriction on PFAS is being considered for which the CSS refers explicitly to this concept.

As noted in the Caracal Paper 1, some references have already been made to the concept of essential use in the framework of two proposals for REACH restrictions on microplastics and PFHxA[16][16], respectively, in both cases to justify exemptions from the

11 CSS p. 10.

12 Regulation 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products, Article 5

13 In order to perform this balance test, the Commission first evaluates the impact on society that non approving the active substance would entail (e.g. social and economic consequences) and then looks at the risks to human health, animal health or the environment that approval would generate. As part of the second branch of the analysis, the Commission takes account of the possibilities to mitigate the risks and compares the risks presented by other active substances that may be used instead. A conclusion is then drawn balancing both evaluations (see Commission Implementing Regulation (EU) 2019/637 of 23 April 2019 approving cholecalciferol as an active substance for use in biocidal products of product-type 14).

14 Commission Decision 2009/395, Commission Decision 2011/48, Commission Decision 2014/85, Commission Decision 2014/395 and Commission Decision 2014/459.

15 Commission Implementing Regulations 2017/1376, 2017/1377, 2017/1378, 2017/1379, 2017/1380, 2017/1381, 2017/1382, 2017/1383, 2019/637

16 See Caracal Paper, page 6

proposed restrictions. It is thus necessary to analyse to what extent the essential use concept can be accommodated within the REACH Regulation as it stands.

In the Caracal Paper 1, the Commission foresees the possibility to apply the concept of essential use either as an "interpretative principle for guidance or as an element to be used in implementing legislation", or as a "new element for decision making" to be included "in co-decision legislation" (see Caracal Paper 1, page 15, section 5, §1). The REACH Regulation is a very broad regulation that imposes various layers of requirements on most chemical substances manufactured or imported into the EU. Registration under REACH applies to all substances manufactured or imported into the EU at 1 ton or more per year, irrespective of their classification as hazardous.

As noted above, the CSS calls for the introduction of the essential use concept for "the most harmful substances" without defining them. "Harmful" does not mean "hazardous" and thus would seem to refer to the notion of "risk", as opposed to "hazard". Indeed, the concept of "hazard" is distinguished from that of "risk" which is defined as the likelihood of harm based on both hazard and exposure. The classification of hazardous substances is one of the purposes of the CLP Regulation, which is considered to be "hazard based". Under REACH, however, only the identification of SVHCs is hazard based, as described below. Other processes address substances of concern, which means that they represent not only a "hazard" but also a "risk". This is the case in particular of the "substance evaluation" and "restrictions" processes. The authorisation process also takes account of the risks of the substances submitted to that process, as discussed below.

As the substance evaluation process is an intermediate process leading to requesting additional information to clarify a concern before this concern is either removed or materialises in proposals triggering the authorisation or restriction process or harmonized classification and labelling ("CLH") decisions under the CLP, substance evaluation does not seem directly relevant for introduction of the essential use concept in the current framework.

We can also rule out the application of the essential concept in CLH decisions. Indeed, a substance will be classified or not on the basis of available data on its hazardous properties; while the CLP allows consideration of the form or physical state in which a substance is placed on the market or expected to be used, there is no scope for making a difference in classification depending upon the essentiality of its uses. By contrast, the REACH authorisation and restriction processes could potentially serve as possible anchors for the implementation of an essential use concept, as discussed below.

1. The Authorisation Process Under REACH

The Authorisation Process under REACH is triggered by the identification that a substance is a CMR or a PBT/vPvB or that it presents an "equivalent level of concern", such as endocrine disrupting chemicals. The legislator has thus predetermined that substances presenting such properties are "substances of very high concern" ("SVHC") and deserve a specific treatment, that is that they should be banned unless authorized, following the REACH authorization process.

This does not mean, however, that the authorisation process is "hazard based". If some categories of SVHCs are identified on the basis of hazard (CMRs and PBTs) others (vPvB) do not have intrinsic hazards. Also, authorities have agreed to first conduct a regulatory management option analysis ("RMOA"), which takes account of the best regulatory option to manage the risks which such hazards may entail. And that risk management option may be a REACH restriction for example. Finally, the authorisation process itself seeks to determine whether the "risks" are adequately controlled or the benefits outweigh the "risks".

One could however consider that SVHCs could be candidate for being among the "most harmful substances" referred to in the CSS for the introduction of the essential use concept. When an economic actor requests authorization for a given SVHC, this authorization is "use specific" and applies only to the applicant. If the applicant can satisfactorily demonstrate that the risks resulting from the use of the SVHC it applies for are "adequately controlled", Article 60.2 of REACH requires that such use "shall be authorized". For uses the risks of which cannot be demonstrated to be adequately controlled, which includes substances for which no thresholds of exposure can be established, such as substances with PBT or vPvB properties, an authorisation may still be

granted under Article 60.4 of REACH but only "if it can be shown that socio-economic benefits outweigh the risks to human health or the environment arisingfrom the use of the substance and if there are no suitable alternative substances or technologies".

It results from the above, that under the current authorization process, the concept of "essential use" could not serve to extend the scope of authorisation to cover other substances of concern, not meeting the criteria of Article 57 of REACH. Also, the concept of "essential use" could not serve to refuse authorisation of uses the risks of which would be demonstrated to be "adequately controlled", which is a mechanistic exercise for threshold substances. These uses indeed "shall" be authorized regardless of whether or not they are "essential" for society. Any deviation from this rule would be illegal.

For uses the risks of which are not adequately controlled, however, there may be scope for the essential use concept within the socio-economic analysis to be conducted as part of the "socio-economic route" for authorisation, as discussed below.

2. The Restriction Process Under REACH

The Restriction Process under REACH requires demonstration that a given chemical substance present "a Community-wide unacceptable risk to human health and the environment (...) which needs to be addressed on a Community-wide basis"[17].The burden of proof that a given substance presents "an unacceptable risk to human health and the environment" lies on authorities.

One could therefore anticipate that substances proved to present an unacceptable risk to human health and the environment would be among the "most harmful substances" considered for the introduction of the essential use concept. In that respect, Article 68 requires authorities to "take account of the socio-economic impact of the restriction, including the availability of alternatives" when deciding on a restriction and therefore the concept of essential use could potentially serve in that context, as discussed in section 3. below, to determine which derogations for particular uses could be granted if the benefits they bring are "essential" to society.

Importantly, however, the essential use concept could not serve to revert or change the fundamental elements of the restriction process, as described above. Thus, the use of a substance could not be restricted without a clear demonstration that the risks it presents are "unacceptable", even if the use is deemed non-essential, and that the adopted measure is proportionate to such risks, considering its benefits to society.

3. Socio-Economic Benefit Analysis

The concept of "socio-economic" benefits is referred to in both the authorisation and the restriction processes, though in different terms. While Article 60.4 allows authorising the use of an SVHC "if it is shown that socio-economic benefits outweigh the risk", Article 68 requires the EU authorities "to take into account the socio-economic impact of a restriction". In the first case, demonstrating socio-economic benefits is a condition of authorisation, while in the second case the socio-economic impact must be "taken into account". Importantly, as does the Montreal Protocol, both articles 60.4 and 68 of REACH also refer to the "availability of alternatives", negatively as a condition to grant an authorisation and positively as an element to take into account in considering a restriction. This is discussed in the Sections 6 below.

Coming back to the nature of the "socio-economic" element of the authorisation and restriction processes, Article 60.4 refers to socio-economic "benefits" outweighing the risks, while Article 68 refers to socio-economic "impact", without further explanation in the preamble or anywhere else.

Does this semantic difference matter? In both cases, a socio-economic analysis must be conducted and essentially allows measuring the "proportionality" of the proposed measure. In the authorisation context, one must compare (i) the risks (of the continued use "benefits" that such use bring to society. In the context of a Restriction, the situation is reversed, since authorities have to compare the benefits of a restriction to its socio-economic "impact".

The socio-economic analysis to be conducted in both the Authorisation and Restriction processes is generally similar as evidenced by Annex XVI of REACH which provides a single description of such analysis for both of these processes. Indeed, Annex

17 REACH Article 68

XVI "outlines the information that may be addressed by those submitting a socio-economic analysis (SEA) with an application for authorisation, as specified in Article 62(5)(a), or in connection with a proposed restriction, as specified in Article 69(6)(b)".

Also, the ECHA Guidance documents on "the preparation of socio-economic analysis as part of an application for authorisation"[18] and on "socio-economic analysis-restrictions"[19] contain generally similar language for the assessment of the economic and social impacts of the proposed measure.

Thus, while there is a difference on the process to be followed leading to the conduct of a socio-economic analysis in the Authorisation and Restriction processes, and on the consequences to be drawn from that analysis, it appears that the socio-economic analysis itself is generally similar, following the criteria of Annex XVI of REACH.

4. Essentiality as Part of a Socio-Economic Benefit Analysis

The next question is whether the concept of essentiality can be accommodated as part of the socio-economic analysis under the REACH authorisation or restriction processes. As noted in the Caracal Paper 1, "currently, socioeconomic assessment in SEAC does not necessarily take into account the concept of essentiality in the sense of criterion 1a of the Montreal protocol (thus the fact that a use is necessary for health or safety or is critical for the functioning of society). Therefore, socio-economic benefits may outweigh the risk also in cases of non-essential uses."[20]

This may be true, but that does not mean that such concept could not find its place as part of a socio-economic analysis. The health and safety and the need to ensure uses that are critical to the functioning of society, can be seen as part of the "social" benefits that must be assessed, to the extent that they have not been covered by the analysis of the "human health and environmental impacts" and "economic impacts" of the measure. The ECHA Guidance Documents on "socio-economic analysis" indeed define "social impacts" as those which may affect workers, consumers and the general public "other than those analysed under the human health and environmental impacts and economic impacts."[21] The ECHA Guidance Documents then specify that these will mainly be impact on employment, employment conditions but also "quality of life (such as change in availability and quality of consumer products)".[22]

Essentiality could therefore fit within such social benefit analysis. However, what is essential remains to be determined and there is an obvious gap between the concept of a used being "critical to the functioning of society" as found in the Montreal Protocol and that of the "quality of life", as referred to in the ECHA Guidance. The Caracal Paper 1 refers the sectors that have consistently been considered "essential" under the Montreal protocol, thus medical uses, fire-fighting, plant/crop protection, aerospace applications, laboratory and analytical uses and process agent uses.[23]

This list is of course far away from encompassing everything that ensures the quality of life, which certainly would include e.g. cosmetics, toys, decorative products, etc. These products may be less "essential" to the "functioning" of society, strictly speaking, but they meet essential societal needs. In fact the Montreal Protocol itself also refers to "cultural and intellectual aspects" as being criterial for the functioning of society, which would clearly go beyond the limited number of sectors mentioned above as being essential. Many industrial products used in other sectors are critical to serve EU strategic objectives such as mobility or digital autonomy and should thus be considered essential.

If products such as cosmetics, toys, or decorative products may be less essential that some medicinal products, they are certainly not worth sacrificing "in bloc", outside of a proper and broad "cost-benefit" analysis that takes account of the specific risks posed by the continued use of substance of concerns in such uses and the loss of quality of life that their ban or restriction would cause.

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18 Guidance on the preparation of socio-economic analysis as part of an application for authorisation, January 2011 (https://echa.europa.eu/documents/10162/23036412/sea_authori-sation_en.pdf/aadf96ec-fbfa-4bc7-9740-a3f6ceb68e6e)

19 Guidance on Socio-Economic Analysis – Restrictions, May 2008 (https://echa.europa.eu/documents/10162/23036412/sea_restrictions_en.pdf/2d7c8e06-b5dd-40fc-b646-3467b5082a9d)

20 Caracal Paper 1, page 11

21 Guidance on Socio-Economic Analysis – Restrictions, May 2008, p. 16; Guidance on the preparation of socio-economic analysis as part of an application for authorisation, January 2011, p.18

22 Guidance on the preparation of socio-economic analysis as part of an application for authorisation, January 2011, p.82

23 Caracal Paper 1, page 9

To conclude, taking into account the "socio-economic consequences" of a restriction (or the socio-economic benefits of an authorisation) could indeed include measurable consequences in terms of job creation or losses, but also loss of availability of products to serve societal needs, including the "quality of life", and thus the importance of such needs. In this context, a concept that would seek to define in which conditions a use or a product is "essential" versus "convenient" - or a "must have" as opposed to a "nice to have" - may find its place. But this can only be considered in comparison of the specific risks that this particular use or product raises, throughout its life cycle, and after an assessment of the possible alternatives is made which is as rigorous as that applied to the potentially restricted substances.

5. Essentiality in the Cousins Paper

Significant efforts have been made by a series of academic authors, led by Ian Cousins, from the Stockholm University, to express their concern over PFAS, to review their uses, and even propose risk management measures to address these alleged concerns, notably based on the concepts of grouping and essential use.[24]

As regards the concept of "essential use", Cousins et al have proposed to set up three categories of essential uses "to aid phase out of non-essential uses of chemicals of concern, exemplified with PFAS uses". These categories are:

(1) Non-essential uses, defined as "uses that are not essential for health and safety, and the functioning of society";
(2) Substitutable uses, defined as "uses that have come to be regarded as essential because they perform important functions, but where alternatives to the substances have now been developed that have equivalent functionality and adequate performance, which makes those uses of the substances no longer essential";
(3) Essential uses, defined as "uses considered essential because they are necessary for health or safety or other highly important purposes and for which alternatives are not yet established".[25]

In doing so Cousins et al. are directly inspired from the Montreal Protocol to arrive at conclusions/proposals that could however not be accommodated as such within the current REACH framework. Indeed, it would not be legally possible under REACH today nor proportionate to determine at the outset that any use of a substance of concern that is not "necessary for the betterment of society in terms of health, safety and functioning"[26] should be banned, irrespective of the availability of suitable alternatives or not. Also, it would be very difficult, if not impossible, to reach a societal or political agreement as to what "betterment for society" concretely means.

The author submits that, under REACH, the use of a substance of concern in a product that serves the quality of life and has no substitute should not be automatically banned or refused authorisation. If it can be demonstrated that the benefits of such product outweigh the risks involved, that use should be authorised as per Article 60.4 of REACH. Otherwise, the ban would be in breach of the REACH Regulation and subject to annulment by the European Courts.

In a restriction, it is for authorities to demonstrate that the impact of the ban of such product will not be disproportionate considering the benefits that the ban would entail in terms of the risks to human health and the environment. Here again an automatic ban of products deemed in advance not to be "necessary for the betterment of society in terms of health, safety and functioning" would also be contrary to Article 68 of REACH and thus illegal.

For example, the Cousins et al. Paper refers to "dental floss, water-repellent surfer shorts and ski waxes" as non-essential uses of PFAS that should be banned[27]. Similarly, the Commission refers in the CSS to the use of PFAS to provide water and oil repellence to textiles, for which a high level of worker protection may be considered essential until suitable alternatives are available, while for consumer uses, "oil repellence could be considered convenient but not essential"[28].

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24 Cousins, Ian T. et al., "The concept of essential use for determining when uses of PFASs can be phased out", Environmental Science :Processes & Impacts 21.11 (2019): 1803-1815 (https://pubs.rsc.org/en/content/articlelanding/2019/em/c9em00163h#!divAbstract)

25 Cousins, Ian T. et al, p. 1805

26 Ibid. p. 1804

27 Ibid. p. 1805

28 European Commission Staff Working Document on Poly- and perfluoroalkyl substances (PFAS) accompanying the Communication from the Commission of 14 October 2020 (COM(2020) 667), Chemicals Strategy for Sustainability Towards a Toxic-Free Environment, p. 9 (https://ec.europa.eu/environment/pdf/chemicals/2020/10/SWD_PFAS.pdf)

We submit that it would not be legal under REACH nor proportionate to ban or refuse authorisation to groups of PFAS substances used in any potentially "non-essential" applications, without a proper socio-economic analysis that takes into account all elements discussed above, including the risks involved with the use of PFAS in those specific applications, the risk management measures taken to control such risks, the socio-economic benefits of such uses, including their impact on the quality of life, and the availability of suitable alternatives.

It should also be considered whether banning such uses for the general public may cause companies to no longer be able to produce in economically viable conditions the equivalent professional products and thus lead to the loss of these products as well, though deemed essential. This also should be part of the analysis of the proportionality of the measure as discussed in Section 7 below.

6. Essentiality and the Need to Analyse Available Alternatives

The Montreal Protocol allows a use to qualify as "essential" if it is necessary for the health, safety or is critical for the functioning of society and "if there are no available technically and economically feasible alternatives or substitutes that are acceptable from the standpoint of environment and health"[29].

As regards this second condition, Article 68 of REACH is more laconic as it only refers to the need to take into account the socio-economic impact of the restriction, "including the availability of substitutes". As regards Article 60.4 of REACH it refers to "suitable alternative substance or technologies", a concept that is further qualified in Article 60.5 of REACH as follows:

"When assessing whether suitable alternative substances or technologies are available, all relevant aspects shall be taken into account by the Commission, including:

(a) Whether the transfer to alternatives would result in reduced overall risks to human health and the environment, taking into account the appropriate

ness and effectiveness of risk management measures;

(b) The technical and economic feasibility of alternatives for the applicant".

In the authorisation context therefore, a qualified alternative must be proved to (1) be "technically and economically feasible for the applicant", and (2) reduce the overall risks to human health and the environment (compared with the substance subject to authorization). It is important to note that the technical and economic feasibility must be assessed on the basis of the conditions applicable "to the applicant" and thus it must be possible (proportionate) for that applicant, technically and economically, to switch to the alternative. This second condition is also fundamental, otherwise this would lead to what is referred to as "regrettable substitutions".

The same conditions should also apply in the context of a restriction under REACH in particular if the "socio-economic" impact to be conducted in that framework is broadened to also take account of a concept of essentiality. Thus, key to the application of the essential use principle will be that a process as rigorous as that used to demonstrated the "concern" of the substances considered for a ban or a restriction be used to determine whether the potential alternative substances or technologies indeed have a better profile in addition to being technically and economically feasible.

7. Essentiality and Proportionality, One of The Main Legal Principles of EU Law

Any decision by the Commission under Article 64.8 of REACH to ban or authorise a substance following the authorisation process or in a restriction adopteunder Article 73 of REACH would be subject to the control of the legality of such measure by the European Courts. In their review, the European Courts would not only rule on the legality of decisions taken on the basis of the essential use concept, with the provisions of the REACH Regulation but also with the Treaty on the Functioning of the European Union (TFEU) and the essential principles of EU Law, enshrined in such Treaty, such as the principles of

29 Decision IV/25 : Essential uses. (https://ozone.unep.org/treaties/montreal-protocol/meet-ings/fourth-meeting-parties/decisions/decision-iv25-essential-us-es?q=es/meetings/fourth-meeting-parties-montreal-protocol/deci-sions/decision-iv25-usos-esenciales)

proportionality, non-discrimination, legal certainty and foresee-ability, legitimate expectations, good administration, etc.

It is beyond the scope of this article to make an extensive review of the possible application of all the EU principles of law to the possible introduction of the essential use concept in the application of Article 60.4 and 68 of REACH. But we review below how the principle of proportionality must be taken into consideration and may invalidate decisions taken on the basis of the essential use concept if applied without due consideration of such principle.

The principle of proportionality requires that measures adopted by EU authorities do not exceed the limits of what is appropriate and necessary in order to attain the objectives legitimately pursued by REACH[30]. In the context of REACH, those objectives include, according to Article 1 of REACH, primarily the protection of human health and of the environment, but also the free circulation of substances on the internal market.

Article 68 of REACH when referring to the need to take into account the socio-economic impact of a restriction, including the availability of alternative, in the restriction process, is clearly underpinned by the principle of proportionality and such principle can then be used to guide the Commission in making its restriction decisions.

As regards Article 60.4 of REACH, it is also inspired from that principle but the REACH text is somewhat more specific in that it imposes upon the authorities to grant an authorisation if the socio-economic benefits of a use outweigh the risks and if there are no suitable alternatives. As described above, on that basis, the simple translation of the Montreal Protocol or of the three categories proposed by Cousins et al. in the implementation of these articles would be contrary to both the REACH text and the principle of proportionality for most uses.

More generally, the principle of proportionality requires that each specific use be analysed and the benefits of its ban or restriction compared with the risks that such specific use represent, thus requiring a case-by-case, use-by-use analysis. For example, it would be disproportionate to ban a use, even if non-essential, of a substance presenting a concern for the environment, if that use would represent virtually no environmental exposure; Indeed, such ban would bring no environmental benefits and thus be disproportionate.

Also, to be proportionate, this analysis must take account of the specificity of each chemical substance being considered. There cannot be a one size fits all restriction that picks up on the characteristics of one chemical to extrapolate it to all other chemicals in a group without positive demonstration of their harmful criteria. Most PFAS for example, are claimed to be persistent or very persistent, and some may be bioaccumulative, but not all. REACH includes criteria for substances that are PBTs or vPvBs showing that it is the addition of persistency and bioaccumulation and/or toxicity which is of concern. It remains to be demonstrated that each and every PFAS meets such criteria of concern or other criteria of concern, provided that these are determined and defined in full transparency and legality.

Otherwise, a ban or restriction will inevitably breach the principle of proportionality, that is the fundamental basis of Articles 60.4 and 68 of REACH, and is an overarching essential principle of EU Law. Importantly also, these essential principles apply not only to decisions taken by the Commission or ECHA in matters of their competence, as specified by the EU legislator in EU legislation such as the REACH Regulation, but these principles also apply to the EU legislator itself.

Indeed, though the Court of Justice has recognized that a certain discretion must be allowed to the legislature when making political, economic and social policy choices that require to carry out complex assessment[31], there is no general exemption with regards to the respect of the general principles of EU law by the legislator. Article 263 TFEU indeed makes clear that "(t)he Court of Justice of the European Union shall review the legality of legislative acts" notably on the ground of "infringement of the Treaties or any rule of law relating to their application"[32]. The EU legislator engaged in a revision of REACH would thus also be required to take due account of all the above considerations as regards the proportionality of the introduction of the essential use concept in a revised EU REACH or other EU legislation.

30 See CJUE, Etimine SA v. Secretary of State, 21 July 2011, §124

31 See CJCE, 12 November 1996, C-84/94, §58, United Kingdom v. Council of the European Union, See also CJCE, 14 December 2004, Swedish Match v. Secretary of State for Health, §48

32 See CJ Stauder v. City of Ulm, 12 November 1969, C-29/69, §7

8. Essentiality Under WTO Rules

The Agreement on Technical Barriers to Trade (TBT Agreement) prohibits technical regulations that are discriminatory or which create unnecessary obstacles to trade. The TBT Agreement leaves however to WTO Members a certain leeway on which legitimate objective (e.g. the protection of human health) they want to pursue providing the technical barrier can pass the necessity test, which is essentially a "proportionality" test.

Under the TBT Agreement, a technical regulation survives the necessity test when it is not more trade-restrictive than necessary to fulfil a legitimate objective. This test has been clarified by the Appellate Body of the WTO through a three prong test which includes:

(a) the degree of contribution made by the measure to the legitimate objective at issue;
(b) the trade-restrictiveness of the measure;
(c) the nature of the risks at issue and the gravity of consequences that would arise from nonfulfillment of the objective(s) pursued by the Member through the measure[33].

The author submits that essentiality as such should not be a "legitimate objective" on its own under the TBT Agreement, and, therefore, EU measure incorporating the concept of essentiality, including specific bans or restrictions on substances for non-essential uses, would need to not be more trade-restrictive than necessary in order to fulfil another objective, such as the protection of human health.

The TBT may thus not easily accommodate a strict view on essential use which would consist in banning all non-essential uses of an harmful substance on the basis of its hazard only, without demonstrating the necessity of such measure to achieve the desired objective.

III. Practical Suggestions for the Introduction of the Concept Under Reach

From the above, the author concludes that it should be possible to introduce the concept of essential use within the socio-economic analysis that is being conducted in the framework of the authorisation and restriction processes of REACH while ensuring that this is done as part of a robust analysis of the proportionality of the proposed measure. This section now addresses some issues related to the concrete implementation of such concept in such socio-economic analysis:

1. Developing Criteria of Essentiality

In the Caracal Paper 1, the European Commission has raised a series of broad questions on existing uses of the essential use concept, examples of essential and non-essential uses, whether decisions should be based on pre-defined criteria or case-by-case assessments, and other substantive and procedural questions. The responses received from the EU Member States and other stakeholders, as summarized in a second document produced by the European Commission for the 38th meeting of CARACAL (the "Caracal Paper 2")[34], show that it will be very difficult to find a consensus on how to approach this issue.

While Member States generally support the introduction of the concept, and the need to define criteria, they also seem to agree that some degree of case-by-case review will be needed. However, beyond that, the initial responses diverge significantly, going from proposing that the concept should be fed at the level of product development so that only products proved to be essential should be marketed[35] to more reasonable suggestions to fit some level of essentiality in the current REACH system[36].

It is beyond the scope of this paper to elaborate a possible definition or criteria for the introduction of the essential use concept under REACH. Neverthe-

33 Report of the Appellate Body – United States – Measures concerning the Importation, Marketing and Sale of Tuna and Tuna Products, WT/DS381/AB/R, 16 May 2012, §322 (https://www.wto.org/english/tratop_e/dispu_e/381abr_e.pdf)

34 European Commission document on "Essential Uses – A possible concept for REACH (Summary of and response to comments to CA/61/2020)" dated 1 March 2021 (CA/14/2021) presented at the 38th meeting of Competent Authorities for REACH and CLP (CARACAL) on 3-4 November 2021.

35 Essential Uses Doc Ca/61/2020, Questions To Caracal, REACH FR competent authority (ministry for the ecological transition) preliminary thoughts, page 2.

36 In the Caracal Paper 2 (page 2), the Commission indicates that it will "develop a working paper on the concept" of essential use and that it is "considering launching a study to continue, amongst other, the legal analysis, assess possible criteria, the scope of application and policy options which will determine the decision making process". At the time of finalizing this article, these working paper and study were not yet available.

less, it is important to stress that the introduction of an essential use concept will need to allow space for science and technology to evolve and new uses to emerge. It will also need to take into account that society and the needs of society are in constant evolution, including in terms of quality of life. An essential use concept should therefore allow for the dynamic adaptation of its scope and assessment criteria as a function of changing societal need and future innovation.

It will therefore be very difficult to arrive at a comprehensive set of criteria that can simply be applied and case-by-case review will certainly be needed, which may make existing procedures even more complex and lengthy, thus far away from the objectives of streamlining the authorization and restriction processes. In that respect, indeed, the Commission indicates in the Caracal Paper as the first advantage of the use of the concept that "some authorisations and restrictions under REACH may be processed faster"[37].

2. Use of Presumptions to Fast Track Essential Uses

One possible way to streamline these processes would be to use "presumptions" as do the (now old) "new approach directives."[38] These Directives establish "essential requirements" and allow EU Standards to be elaborated to demonstrate compliance with such requirements. Products that comply with EU standards are "deemed" in compliance with the essential requirements, but compliance can be also demonstrated by other means.

The proposal would therefore be to agree on a set of rules to define at the outset what products and applications should be "deemed essential" and could be fast tracked for rapid decision making. Possibly rules could also be set up at the outset to define which products are "deemed not to be essential". In both cases, rules would also be set up to reverse these presumptions, also specifying who has the burden of proof to do so.

Products subject to such presumptions, while undergoing a case-by-case analysis, would nevertheless be fast tracked when considering a request for authorisation or a proposal for a restriction, as part of the socio-economic analysis. This may lead to the authorisation of such uses, to their being excluded from the scope of the proposed restriction or exempted from the later.

In that framework, essentiality could be assessed starting with the EU strategic objectives and the determination of the product needed to achieve those objectives. Substances of concern necessary for the functionality of such strategic products would be deemed essential and fast tracked for authorization or exemption from proposed restrictions, unless suitable alternatives would be demonstrated to exist.

For example, chemical substances needed to ensure the functioning of batteries for electric vehicles that are key to ensure the EU green mobility, a strategic EU objective, would be "deemed essential" and thus authorized or exempt from restriction under REACH if such substances would come to be subject to such processes (like some Lithium compounds)[39], unless and until alternative substances or technologies presenting less health or environmental risks would be developed that become economically and technically feasible.

Essential products so authorized could still be subject to risk management measures to limit exposure to the extent possible during production, use and at the end of their life. The process could for example facilitate authorization for products produced in sites that comply with EU Eco-Management and Audit Scheme (EMAS)[40] or that meet the future sustainability by design requirements.

This would be a pragmatic way to ensure that not only the protection of human health and the environment but also the strategic objectives of the EU, including those in the Green Deal, are met and that the processes are streamlined to that effect. By contrast, in the past years, antagonistic goals, pursued by different parts of the European Commission, have driven in different directions, with industry having to defend under REACH processes products that are deemed essential to meet EU strategic goals.

37 Caracal Paper 1, Page 7.

38 See the Guide to implementation of Community harmonization directives based on the new approach and the global approach, October 1994 https://op.europa.eu/en/publication-detail/-/publica-tion/3d49c4e8-03de-4a9a-ab41-5d18721eea8a/language-en/for-mat-PDF/source-search

39 lithium carbonate; lithium chloride; lithium... - Registry of CLH intentions until outcome - ECHA (europa.eu)

40 EMAS – Environment - European Commission (europa.eu) (https://ec.europa.eu/environment/emas/)

For other products that are not "strategic", the normal REACH process would apply with a proportional analysis of the socio-economic impact of the proposed measure, taking into account societal needs and leaving the door open for the satisfaction of future needs.

Finally, for categories of products that could be "deemed not to be essential", the bar would be set higher, in accordance with the principle of proportionality, for producers and users to demonstrate that the use of substances of concern remains beneficial, possibly also following a fast-track system leading to their ban or restriction unless these stricter conditions can be demonstrated to be met.

It will remain to be determined how far can the European Commission lawfully go in developing criteria that could allow fast tracking the review of essential or non-essential uses under the current REACH Regulation processes and whether this could be done in the form of guidance, or via an implementing regulation or whether an amendment to the REACH Regulation would be needed. Provided that the decisions taken in the authorization and restrictions processes duly follow the establish processes and maintain a case-by-case review that respect the conditions set forth in the legislation and the principle of proportionality, a guidance on essential uses could be elaborated to serve in the socio-economic assessment that is required under REACH. The criteria for socio-economic assessment of Annex XVI of REACH would seem sufficiently flexible to accommodate this, even if a reference to the essential use concept via an amendment of such Annex would provide useful additional legal support.

IV. Conclusion

The question of "essentiality" is not limited to chemical regulation. It is also a concept that is largely referred to in the context of the Covid-19 pandemic. And everyone could observe with the different answers given in the different countries to the very same questions, how relative and diverse are the perceptions that one has on which human activities are essential or less essential in that context.

The author submits that the concept of essential use could be legally applied under REACH but only under the REACH authorization and restriction processes for substances of concern that present an unacceptable risk and are not adequately controlled and that are today subject to a socio-economic analysis and an analysis of alternatives.

Great care should however be taken by authorities to avoid products being banned on the basis of subjective judgements of what is good or bad for society. Indeed, banning the use of substances in products on the basis of subjective judgements would lead to arbitrary, discriminatory and/or disproportionate decisions that breach essential EU legal principles and could thus be legally challenged.