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Circular Economy & Green Growth
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Concerns: **Essential Uses**

Agenda Point: **4.3**

Action Requested: **Competent Authorities and observers are invited to comment on the document and the discussion points put forward. Written comments should be sent by 7 January 2021 to:**
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1. INTRODUCTION

The Chemicals Strategy for Sustainability (CSS) adopted on 14 October 2020 proposes to extend the use of generic approaches to risk management to *"ensure that consumers, vulnerable groups and the natural environment are more consistently protected, while still allowing for the use of these most harmful chemicals where proven essential for society. The criteria for essential uses of these chemicals will have to be properly defined to ensure coherent application across EU legislation, and will in particular take into consideration the needs for achieving the green and digital transition."*

Furthermore, the CSS announces that the Commission will *"define criteria for essential uses to ensure that the most harmful chemicals are only allowed if their use is necessary for health, safety or is critical for the functioning of society and if there are no alternatives that are acceptable from the standpoint of environment and health. These criteria will guide the application of essential uses in all relevant EU legislation for both generic and specific risk assessments.". The Strategy's action plan indicates that the criteria for essential uses will be defined in the period 2021-22.*

On the basis of the above-mentioned provisions of the CSS, this document aims to launch the discussion in CARACAL about the concept of essential uses. For this purpose, it first provides available information about the current use of essential use concepts in different contexts, including the Montreal Protocol, It briefly describes the essential use concept established under the Montreal Protocol and its practical application. It provides a comparison between this essential use concept and the REACH processes, and identifies lessons that may facilitate the REACH processes. Under REACH, granting of authorisation is conditional on either achieving adequate control (Article 60(2)), or alternatively demonstrating that no suitable alternatives are available and that the socio-economic benefits of continued use of the substance outweigh the risk (Article 60(4)). Where there is an unacceptable risk to human health or the environment, restrictions shall be adopted, taking into account the socio-economic impact of the restriction, including the availability of alternatives (Article 68(1)).

While those provisions do not explicitly refer to the type of uses for which authorisation may be granted, or for which potential derogations from restrictions may apply, the socio-economic analysis performed within those provisions indicates the net value for society rendered by those uses and thus pointing out whether society is better off or not with certain uses (from a socio-economic point of view). Discussions have arisen whether the use of the most hazardous or persistent substances should not be further restricted to uses with a high societal value, or in other words "essential uses".

It needs to be emphasised that this document does not contain any specific proposal. Comparing certain criteria under REACH with some of those established under the Montreal Protocol for ozone depleting substances (ODS) and identifying potential areas where lessons may be learned does not suggest that it would be conclusive to apply those in REACH.

Furthermore, this document is about the use of an essential use concept under REACH. It does not yet consider that the criteria have to be defined for coherent application across EU legislation.

The Commission invites CARACAL to have an initial exchange of views on the topic before actually starting the development of an essential use concept as envisaged by the CSS. This discussion would trigger the necessary reflection process to identify questions and challenges that will need to be resolved to be able to apply the concept in REACH.

Therefore, the Commission invites Member States and observers to identify additional information and considerations that will be relevant for the further discussion of the concept of essential uses and of its criteria.

Owing to the need for brevity, some descriptions in this document may not fully cover all possible aspects of a situation. It is presumed that CARACAL members and observers are sufficiently familiar with the REACH procedures and that there is thus less need to go into details.

2. BACKGROUND

The concept of essential uses by the Montreal Protocol[1] acknowledged that for a small fraction of ODS uses it would be more difficult to phase them out and that their phase out would have to be handled separately from the agreed phase-out schedule. This mainly concerned uses in health and security sectors and where the use was seen as important for the functioning of society, and for which it was not immediately evident that there would be suitable alternatives available at that moment in time. It reassured the Parties to the Montreal Protocol that ODS for these 'essential uses' would remain available until technically and economically viable solutions became available[2]. This acknowledgement and reassurance allowed Parties, industry and consumers to focus on a rapid phase out of the majority of ODS uses compared to a situation where all ODS uses would have had the same standing.

While not enshrined in European Union chemicals legislation as a general concept, apart from the ODS-Regulation, in practice similar decision making processes are typically applied in legislation where a general rule is established and, if appropriate, special derogations or exemptions are added. In the context of REACH, for example, the authorisation process allows for the continued use of Substances of Very High Concern (SVHC) in specific cases where suitable alternatives are not available and where the socio-economic benefits of the use outweigh the risk from that use. The socio-economic assessment already covers to a certain extent the aspect of an essential use concept, albeit using different criteria from those used by the Montreal Protocol.

2.1. Drivers for discussing essential uses

In academic and political circles an essential use concept is increasingly discussed as a tool for chemicals risk management under REACH, in particular in the context of the phase-

[1] Montreal Protocol on Substances that Deplete the Ozone Layer (1987), https://ozone.unep.org/treaties/montreal-protocol

[2] Note: for methyl bromide and halon uses it has become customary in the Montreal Protocol environment to refer to 'critical uses' instead but in essence there is no difference in the management. For the purpose of simplification, readability and to minimise confusion, this document uses only the term 'essential uses'.

down of PFAS uses. This section outlines further some of the drivers that contributed and eventually led to the inclusion of an essential use concept in the Union's new CSS.

2.1.1. The Madrid Statement and subsequent activities

In the Madrid Statement on Poly- and Perfluoroalkyl Substances[3], scientists in 2015 pointed out that some PFASs have been listed under the Stockholm Convention[4] as persistent organic pollutants (POPs). The Statement refers to the Montreal Protocol and called on product manufacturers to stop using PFAS where they are not essential or when safer alternatives exist. It was pointed out that, "*while many fluorinated alternatives are being marketed, little information is publicly available on their chemical structures, properties, uses, and toxicological profiles*."

Since the Madrid Statement, several scientific papers[5] discussed the issue of using an essential use concept to manage the risk from PFAS. Most recently, the Stockholm University organised a panel discussion[6].

Similarly, experience gained during the preparation of REACH restriction dossiers has demonstrated that, it is often very difficult for the risk assessors preparing dossiers for authorities to obtain specific and reliable information, for example on the costs and benefits of each use, at the necessary level of detail. This is especially true for substances, such as PFAS, used in many sectors and for which not all uses are known. This makes it very difficult to assess the need and, where appropriate, the right level of legislative or non-legislative risk-management action.

The absence of robust, reliable and uncontested data is one of the factors increasing significantly the timeframe and the resources required to develop and process relevant dossiers.

2.1.2. Council Conclusions

In 2019 the Council of the European Union adopted the Conclusions "Towards a Sustainable Chemicals Policy Strategy of the Union" in which the Council, amongst others, "*CALLS on the Commission to develop an action plan to eliminate all non-essential uses of PFAS*"[7].

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3 Madrid Statement on Poly- and Perfluoroalkyl Substances (PFAS), https://ehp.niehs.nih.gov/doi/10.1289/ehp.1509934

4 Stockholm Convention on persistent organic pollutions (POP), http://www.pops.int/TheConvention/Overview/TextoftheConvention/tabid/2232/Default.aspx

5 For example: 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://doi.org/10.1039/C9EM00163H)

6 ACES Seminar series: Panel discussion on PFAS and the Essential Use concept (https://www.aces.su.se/events/aces-seminar-series-panel-discussion-on-pfas-and-the-essential-use-concept/) summary available at (https://www.aces.su.se/news/launch-of-departments-new-seminar-series-a-great-success/)

7 Council Conclusion of 26 June 2019 "Towards a Sustainable Chemicals Policy Strategy of the Union, https://www.consilium.europa.eu/en/press/press-releases/2019/06/26/council-conclusions-on-chemicals

2.1.3. Resolution of the European Parliament

On 10 July 2020 the European Parliament has adopted a Resolution on the Chemicals Strategy for Sustainability[8] in which, amongst others, it:

> *72. Urges the Commission to set firm deadlines in the action plan on perfluoroalkylated substances (PFAS) so as to ensure the speedy phasing out of all non-essential uses of PFAS, and to accelerate the development of safe and non-persistent alternatives to all uses of PFAS as part of the Chemicals Strategy for Sustainability;*
>
> *73. Calls on the Commission to define the concept of and criteria for the 'essential use' of hazardous chemicals, taking the definition of essential use provided in the Montreal Protocol on Substances that deplete the Ozone Layer as a basis, so as to provide a harmonised approach for regulatory measures on non-essential uses;*

2.1.4. Discussions in the context of REACH restriction dossiers

In their proposals for restrictions, dossier submitters refer increasingly to the concept of essential uses, for example:

- The ECHA dossier for the restriction of microplastics[9], targets the use of microplastics that are intentionally added to consumer and professional products. The concept of essential use is brought forward in the SEAC discussion. SEAC refers to the concept as an additional element to consider in deciding on the proportionality of the restriction and the need for derogations for specific uses (cosmetics or in-vitro diagnostic kits).

- The proposal by Germany for a full ban of the manufacture and placing on the market of undecafluorohexanoic acid (PFHxA), its salts and related substances[10] above certain concentrations. The restriction proposal alludes to the concept of essential uses in several instances as a means to justify a number of derogations to the restriction, i.e. personal protective equipment and non-woven medical textiles. For these two categories, the dossier submitter has identified the use of PFHxA as essential where alternatives do not meet the properties needed with regard to oil and/or dirt repellence, based on that the lack of these properties would lead to unacceptable health risks for certain product user groups, most likely leading to high societal cost.

2.2. Potential advantages of defining and introducing the concept of essential uses (non-exhaustive)

A clear definition of the concept of essential uses could have benefits such as simplification in some cases:

- Some authorisations and restrictions under REACH may be processed faster, as the concept will facilitate decision making by the Commission and Member States. For example, as it will be clearer for dossier submitters, which authorisation requests and

[8] European Parliament resolution of 10 July 2020 on the Chemicals Strategy for Sustainability, https://www.europarl.europa.eu/doceo/document/TA-9-2020-0201_EN.html

[9] https://echa.europa.eu/registry-of-restriction-intentions/-/dislist/details/0b0236e18244cd73

[10] https://echa.europa.eu/fr/registry-of-restriction-intentions/-/dislist/details/0b0236e18323a25d

restriction proposals are likely to be approved, this may facilitate, *a priori*, the assessment of requested uses and of possible derogations from restrictions;

- It would ensure that authorisations and exemptions from restrictions will be made taking into account considerations about their essentiality;

- If authorisations and exemptions from restrictions were no longer granted for uses that are considered non-essential, it is hoped that the objective of moving towards a toxic-free environment will be achieved faster;

- It could be used by third countries as an example to strengthen their environmental standards;

- Less pollution will reduce the impact of the relevant substances, including but not limited to environment and health;

- More predictable decision-making process on authorisations and restrictions.

2.3. Potential disadvantages of defining and introducing the concept of essential uses (non-exhaustive)

- Banning or restricting uses of substances on the basis of their essentiality, without sufficient assessment of the impacts may lead to regrettable substitution or impaired competitiveness and innovation.

- It may render certain uses of value for the society as non-essential, and thus prevent society from benefitting from the convenience or utility of those uses.

- Considering the concept will further restrict the use of certain chemicals within EU, it may result in deterioration of the level-playing-field for EU producers as compared to non-EU producers and may lead to exporting pollution and transferring health and environmental impacts outside the EU;

- An essential use concept might limit people's choices.

- It may lead to 'de facto' regulating products or people's preferences.

Only once the potential advantages and disadvantages of variations of the essential use concept have been sufficiently debated, challenged and assessed, it will be meaningful to investigate in what way a consensus form of the concept can be best deployed (self-regulation, legislation, guidance, standards, etc.).

3. THE MONTREAL PROTOCOL

The Montreal Protocol on Substances that Deplete the Ozone Layer is a Multilateral Environmental Agreement to protect the Earth's ozone layer by phasing out the chemicals that deplete it. It covers both the production and consumption of ozone-depleting substances. The Montreal Protocol is generally considered as the most successful international environmental agreement. It was ratified by all UN Member States making it

the only treaty with global ratification. Signed in 1987 and entering into force in 1989, its mechanisms have inspired many other environmental agreements.

This chapter briefly describes the essential use concept under the Montreal Protocol and compares it to REACH authorisation and restriction procedures.

3.1. The essential use concept under the Montreal Protocol

One of the features of the Montreal Protocol is the concept of essential use, put in place to assess applications for exemptions from the phase out requirements. To this extent, the Fourth Meeting of the Parties decided, in Decision IV/25[11]:

[…]

(1) that a use of a controlled substance should qualify as "essential" only if:

(a) it is necessary for the health, safety or is critical for the functioning of society (encompassing cultural and intellectual aspects); and

(b) there are no available technically and economically feasible alternatives or substitutes that are acceptable from the standpoint of environment and health.

(2) that production and consumption, if any, of a controlled substance for essential uses should be permitted only if:

(a) all economically feasible steps have been taken to minimize the essential use and any associated emission of the controlled substance; and

(b) 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;

[…][12]

Parties requesting a particular use to be considered as essential, need to submit a corresponding application nine months (six months in case of halons) prior to the relevant Meeting of the Parties.

The application is assessed by the Technology and Economic Assessment Panel (TEAP) that consists of experts nominated by the Parties and approved by the Meeting of the Parties. Following the consultation of its experts in the relevant Technical and Economic Options Committee (TOC), TEAP will provide a report of its findings and a

[11] UNEP, 'Handbook for the Montreal Protocol on Substances that Deplete the Ozone Layer', 13th Edition (2019). Decisions on Essential Use, Decision IV/25: Essential Uses, para. 1(a), https://ozone.unep.org/treaties/montreal-protocol/meetings/fourth-meeting-parties-montreal-protocol/decisions/decision-4

[12] Note: the term "safety" is to be understood as comprising also security (e.g. policing, defence, fire-fighting)

recommendation at least 3 months ahead of the relevant Meeting of the Parties, i.e. it typically completes the assessment within six months (three for halons).

The Meeting of the Parties will then discuss any proposal based on the findings of TEAP and decide whether or not to approve the use as essential and the related conditions on a case by case basis. However, for some uses occurring in many Parties (laboratory uses, process agent uses), a 'global exemption' approach was taken to avoid a large number of individual applications. A global exemption defines a set of uses that are considered as essential under the specified conditions. In this context "global" is more to be understood as "world-wide", i.e. in all Parties, and not as "everything" or "general".

The sectors and uses which would be considered essential materialised relatively early in the discussions of the Parties and did not change since. Therefore, there has not been a need for TEAP to assess the criterion 1a for each case individually. When taking a closer look at the type of uses the Parties to the Montreal Protocol considered as necessary for the health, safety or as critical for the functioning of society[13], there is a striking resemblance to what is considered as "essential" under Union legislation (see chapter 4):

(1) Medical uses (mostly related to the use of ODS as propellant in metered dose inhalers to treat pulmonary diseases)

(2) Fire-fighting (uses of halons and HCFC in fire-fighting)

(3) Plant/crop protection (mainly the use of methyl bromide for fumigation purposes)

(4) Aerospace applications (mainly ODS used as solvents)

(5) Laboratory and analytical uses (not limited to research and development)

(6) Process agent uses (a short list of processes in which the replacement of ODS was technically or economically not feasible)

Generally, the Meeting of the Parties follows the relevant TEAP recommendations. Even if in some cases details are being fiercely negotiated, overall the Parties succeeded in developing a pragmatic approach.

3.2. Montreal Protocol vs. REACH authorisation and restrictions

This section aims at describing similarities and differences between the essential use concept under the Montreal Protocol and the REACH authorisation and restriction processes. As the two instruments have different starting points and objectives, this section does not evaluate them, rather only identifies areas which may or not be relevant for lesson learning without suggesting that there may be deficiencies in the instruments in these aspects.

3.2.1. Basic risk management aspects

Under the REACH authorisation process, it is either demonstrated that the risk from an authorised use is adequately controlled and that a substitution plan is submitted if there

[13] Note: The decisions of the Meetings of the Parties to the Montreal Protocol did not systematically use the term "essential use" for all derogations granted in line with Decision IV/25. Some uses are referred to as critical uses. This is ignored in the list for the sake of readability.

are suitable alternatives or – that, if there are no suitable alternatives, benefits outweigh the risks (which in any case need to be reduced as much as possible, e.g. through a closed system, risk management measures, including as a last resort personal protection equipment). It appears that, under the Montreal Protocol there is more emphasis on phasing out by allowing only uses required for health, safety and the functioning of society, while REACH considers both risk reduction and phasing out.

The scenario for REACH restrictions is more diverse as restrictions can take various forms. The base assumption is that in case of a risk to human health or the environment that is unacceptable, not adequately controlled and needs to be addressed on a Union-wide basis, this results in a restriction. These decisions need to consider their socio-economic impact, including the availability of alternatives. In comparison, this is similar to the criteria under the Montreal Protocol. Like for bans and restrictions in other pieces of legislation, it can be assumed that fully restricted (= banned) uses are not essential because it would be irresponsible to fully restrict uses that are necessary for health, safety or critical for the functioning of society in the absence of alternatives. In this sense, derogations from restrictions may give an indication that the relevant use may be essential.

Essential use nomination under the Montreal Protocol - Example

A relatively simple example to depict the process is the 2015 Essential Use Nomination by China for the use of carbon tetrachloride (=Tetrachloromethane) for laboratory and analytical uses:

Essential use nomination communicated to Parties:
https://ozone.unep.org/system/files/documents/OEWG-36-2E.pdf, see paragraph 7 on page 2

TEAP Assessment:
https://ozone.unep.org/sites/default/files/2019-05/TEAP_Progress_Report_June_2015.pdf, pages 9-11

Decision eventually taken by the Meeting of the Parties:
https://ozone.unep.org/treaties/montreal-protocol/meetings/twenty-sixth-meeting-parties/decisions/decision-xxvi4-essential

3.2.2. Criterion 1a of Decision IV/25

Under the Montreal Protocol process the Decision IV/25 requires in criterion 1a that the use *is necessary for the health, safety or is critical for the functioning of society (encompassing cultural and intellectual aspects)*.

In REACH authorisation and restriction processes, although the aspects of criterion 1a are not explicitly framed as such, they are considered within the socio-economic assessment, which also encompasses other aspects. They intend to ensure that the relevant risk can be controlled or that the socio-economic benefits outweigh the risks in the absence of suitable alternatives. Consequently, uses could be authorised or exempted from restrictions,

without a limitation of the assessment explicitly and solely to their necessity for health, safety or criticality for the functioning of the society.

Under the Montreal Protocol the use of ODS is a priori not acceptable, even if the risk is small, due to the significant global environmental and health impact. Derogations are, therefore, only possible where otherwise a severe impact on health, safety and the functioning of the society would occur. It should be noted that there were no nominations by Parties for uses related to luxury, convenience, leisure, cosmetics, toys or decorative products, to name a few examples.

Currently, socio-economic assessment in SEAC does not necessarily take into account the concept of essentiality in the sense of criterion 1a of the Montreal protocol. Therefore, socio-economic benefits may outweigh the risk also in cases of non-essential uses. This has led to criticism for some authorisations and exemptions from restrictions as it was considered that those uses were not necessary for health, safety or critical for the functioning of society.

3.2.3. Objective and methods

The authorisation process aims to ensure that the risks related to SVHC are properly controlled throughout their life cycle, and to promote the progressive replacement of SVHC by suitable alternatives (less dangerous substances, new technologies and processes), where technically and economically feasible alternatives are available.[14]

The common elements with the Montreal Protocol are:

- the objective of eventually ending the use of the chemical concerned.
- uses are only tolerated if no suitable alternatives exist that are technically and economically feasible.

However, there are also differences with the Montreal Protocol, under which:

- phase out is the main risk management mechanism (REACH is more nuanced).
- during its assessment of exemption requests, TEAP does not establish risk levels and there is no discussion on whether or not the risk from ODS is acceptable.
- typically there are no user specific measures but a national consumption limit is set. It is up to the Parties how they stay within the set use limit. A mechanism is established to deal with emergency needs[15].

[14] REACH Article 55

[15] An emergency need concept exists in several pieces of Union legislation, e.g. in the ODS or in the Pesticide Regulation. While emergency need concepts may be part of an essential use concept, they are not an essential use concept as such, as they do not necessarily consider criterion 1b.

3.2.4. Not-in kind alternatives / Alternative Technologies

Not-in-kind alternatives are alternatives that go beyond the simple exchange of a chemical with a less hazardous chemical (with only minor adjustments to the process if at all), so-called drop-in alternatives. Instead, a completely different process or technology is used to achieve the objective[16]. Some examples are provided in the text box below.

Both instruments strive for considering all sorts of possible alternatives (alternative chemical substances, technologies, processes) that could replace relevant substances, including not-in-kind alternatives (terminology used in the Montreal Protocol) or alternative technologies (terminology used in REACH).

Not-in-kind substitution - Examples

A very classic example for a not-in-kind substitution of ODS is the replacement of deodorants applied in form of an aerosol (i.e. an aerosol using ODS as propellant). The drop in alternative is the use of a non-ODS propellant (still today typically substances with a global warming potential). The not-in-kind alternative were roll-on devices to the market.

A more sophisticated example is air-conditioning. Again, the drop-in alternatives are substances with a global warming potential. More recently so-called natural refrigerants enter the market that have a low or no climate impact but require higher product safety standards. The non-in-kind alternative is building houses in a way that reduced the need for air-conditioning or makes it obsolete altogether (e.g. energy efficient houses).

A recent, not ODS related example, is single-use plastic. An in-kind alternative to a shampoo container made of traditional plastic is the use of recycled plastic or sales via bulk shops. The not-in-kind alternative is a solid shampoo bar that can be wrapped in paper, a card box or even be sold without individual packaging.

3.2.5. Process

In terms of process, both instruments leave the technical assessment of the case to an expert body that provides recommendations or opinions to the decision taking body, which will discuss the cases further prior to taking a decision.

3.2.6. Conclusion

While the two instrument have different backgrounds, scope and objectives, there are elements from the Montreal Protocol that may assist in developing a similar concept for REACH procedures.

[16] Functional substitution would be a similar concept

3.3. Possible Lessons to be learnt

This section outlines possible lessons that can be learnt from the Montreal Protocol to attain the objectives of REACH (see Article 1) more efficiently, including also, more specifically, the objective of progressively substituting SVHC in the context of Article 55 (i.e. where suitable alternative substances or technologies are economically and technically viable).

Also for the broader concept of 'substances of concern', there are lessons that may have the potential to facilitate a more rapid advancement towards a toxic-free environment.

The assessment of alternatives is already part of the current SEAC assessments, therefore this aspect of essentiality, i.e. criterion 1b, does not need to be further discussed. This section puts focus on the added value that criterion 1a may offer.

3.3.1. Criterion 1a: health, safety or critical for the functioning of society

As outlined above, the assessment whether a use is necessary for health or safety reasons or is critical for the functioning of society (encompassing cultural and intellectual aspects), is currently not explicitly framed as such in the decision-making process under REACH, although it is considered under the socio-economic analysis, which also includes other elements.

A pre-decision on political level[17] on what might constitute an essential or a non-essential use in the context of criterion 1a, could inform and allow focussing resources on cases that are of higher relevance for attaining the REACH objectives. Following the example of the Montreal Protocol when applying an essential use concept in practice, would mean taking a decision on criterion 1a primarily on a political level and not on a case-by-case basis as part of the RAC and SEAC considerations, although their findings with regard to essentiality in a specific case could further inform the case specific decision-making process.

One option is to develop definitions and criteria on how to apply criterion 1a or a similar criterion in the context of REACH which will define uses that will e.g. always, never, likely or not likely be eligible for an authorisation or an exemption to a restriction,. This may facilitate an easier and faster, decision making process.

Such pre-decision on a political level would be a step preceding the case-by-case assessment.

4. EXISTING ESSENTIAL USE CONCEPTS IN UNION LEGISLATION

Some pieces of European Union legislation include implicit references to essential and non-essential uses. Mostly, where in light of the precautionary principle, it was considered an unacceptable risk to place relevant products on the market. Examples include the ban

[17] At this moment in time the document leaves it deliberately open what the nature or format of this political decision may be as not to pre-empt any outcome of the discussions on this topic. The nature of the concept that may be developed will later in the process lend itself to a specific solution.

of CMR substances in toys and cosmetics. Such legislation and the decisions taking therein by the legislator can frame an essential use concept and inspire a definition of essentiality in the context of REACH.

The Commission has long been engaged in supporting the protection of critical infrastructure from all kind of threats, be it natural or man-made disaster or terrorist attacks[18]. In 2004 the European Council tasked the Commission with preparing a strategy for the protection of critical infrastructure. In this context the Commission listed examples of critical infrastructures which include[19]:

(1) Energy installations and networks

(2) Communications and information technology

(3) Finance

(4) Healthcare

(5) Food

(6) Water

(7) Transport

(8) Production, storage and transport of dangerous goods

(9) Government

This list of sectors, which was also carried over to the subsequently adopted European Programme for Critical Infrastructure Protection (EPCIP)[20], gives some indication what kind of activities the EU is considering as so critical for the functioning of society that they must remain in service at all times.

Uses of relevant substances without alternatives in these areas may also be considered essential for health, safety and the functioning of society.

It must be pointed out, though, that the EU policy on critical infrastructure protection derives from a (homeland) security angle, and criticality in a security context does not necessarily mean that the infrastructure provides an essential service.[21] On the other hand, as not all essential services are equally vulnerable from a security point of view, probably not all essential uses are listed as 'critical'. Moreover, taking into account the limited EU

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18 Directorate General for Migration and Home Affairs, Critical Infrastructure Protection website (https://ec.europa.eu/home-affairs/what-we-do/policies/counter-terrorism/protection_en)

19 Critical Infrastructure Protection in the Fight against Terrorism, COM (2004) 702, 20.10.2004, pg.4, (https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2004:0702:FIN:EN:PDF)

20 European Programme for Critical Infrastructure Protection (https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=LEGISSUM:l33260&from=EN)

21 It may also comprise infrastructure in need of particular protection, e.g. as an attack on those may cause particular harm to health or the environment (and subsequently health), Such scenarios include, for example, the poisoning of a water reservoir or a bomb attack on a chemical plant releasing highly toxic gas. Therefore, it is not possible to conclude automatically that all uses in the listed sectors are truly essential.

competence in the field of security and emphasizing the principles of subsidiarity and complementarity, the focus of the European Programme for Critical Infrastructure Protection is on infrastructure that is critical mainly from a European, rather than a national or regional perspective. This means critical uses of substances in specific sectors at national or regional level might not be addressed by the EU policy on critical infrastructure protection but still generally be considered 'essential'.

As outlined above (see 3.1) this EU list of critical infrastructure sectors is quite similar to the list of essential uses that have evolved under the Montreal Protocol. There is also resemblance to the uses exempted in the context of the Regulation on Persistent Organic Pollutants[22]. Interestingly, in their paper "The concept of essential use for determining when uses of PFASs can be phased out", Ian T. Cousins et. al. also draw similar conclusions[23].

A more in depth analysis of relevant legislation would be required before drawing final conclusions.

5. THE POTENTIAL APPLICATION OF THE ESSENTIAL USE CONCEPT AND THE ROLE OF THE DISCUSSION IN CARACAL

In principle, the essential use concept could be applied within the existing legal framework, as an interpretative principle for guidance or as an element to be used in implementing legislation, or be included in co-decision legislation, as a new element for decision-making on the use of the most hazardous chemicals. It could apply within REACH but it is also relevant for other pieces of chemicals legislation (e.g. food safety, toys, cosmetics).

As the potential use of the concept is a complex question that will require discussions at various levels, the purpose of this paper and the discussion at CARACAL is not to decide on whether and which uses will be made of the concept. Rather, the paper aims to inform CARACAL about the elements which the Commission is considering when developing the concept for the purpose of REACH and invites Member States and observers to identify additional information and considerations that will be relevant for the further work on the concept. The discussion at CARACAL should also trigger a reflection and discussion process to identify questions and issues that will need to be resolved before applying the concept within REACH

6. CONSIDERATIONS AND CHALLENGES

During the development process there are a number of aspects that will have to be kept in mind (non-exhaustive):

- It is not necessarily evident what use is considered as essential or not by the society and there may often be differences of opinions on what is essential and

[22] Regulation (EU) 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants (Text with EEA relevance.), PE/61/2019/REV/1, OJ L 169, 25.6.2019, p. 45–77, (https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32019R1021)

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

what not. Therefore, objectivity and relevance of the definition and criteria must be ensured.

- When discussing an essential use concept it will of course remain relevant – as in today's decision-making processes – not to assess chemicals or uses of chemicals individually but also see their context in order to avoid regrettable substitution.

- The scope of REACH is much broader than the Montreal Protocol and the related uses are much more diverse and far-reaching, therefore even more difficult to pre-define what is essential and what not. Therefore, the relevance of the scope of application should be considered.

- The COVID-19 crisis has demonstrated that the concept of what is considered essential is not necessarily evident and may change over time. It is necessary to remain able to respond to changing and innovation needs. This may not only include technical progress but also political needs, e.g. to facilitate the transition to a sustainable society, potentially even at the cost of using a SVHC.

- Is the additional technical benefit of an SVHC in a product or process, compared to an available alternative, sufficiently large to justify the continued use of an SVHC? Consumers may or may not be prepared to sacrifice a certain degree of performance or quality for environmental or human health benefits.

- In light of global economic changes, it would have to be discussed to what extent 'availability' of an alternative can be assumed, if the alternative is produced e.g. in unreliable partners or under questionable conditions (e.g. exploitation of workers, weak environmental standards).

- Whether concepts such as critical raw materials or strategic chemicals can further inform about what uses might be considered essential for the functioning of society.

- The right balance has to be found between political pre-decisions and the need for objective and appropriate assessments.

- The level playing field for EU producers compared to non-EU producers needs to be ensured.

- The concept should allow differentiation between uses within sectors, whereas some uses within the same sector can be essential and others not.

7. QUESTIONS TO CARACAL

(1) Have there been efforts in your Member State / Association to define a concept of essential uses or a similar concept to address REACH restrictions or

authorisations or in the framework of another legislation? If yes, please explain.

(2) Are you aware of scientific or other kinds of documents that address the concept of essential uses and that have not been referred to in this document or its annex?

(3) Are you aware of legislation or other regulatory procedures that use a concept like essential uses and that are not referred to in this document?

(4) What are the challenges for the use of the concept? Who will decide on essentiality for society and how can this decision be made?

(5) Could you think of examples (ideally with a short justification):

(a) where it may be easy to define whether uses are essential or not (or likely to be essential or not)?

(b) where you believe it would be important to work on applying the concept on essentiality?

(6) To what degree shall decisions be taken on the basis of pre-defined essentiality criteria only and to what degree do decisions still need case-by-case assessments?

(7) Are there aspects that you would consider important to investigate during the development of an essential use concept and that have not yet been mentioned?

(8) Do you have initial ideas on criteria or definitions that might help to decide whether a use might or not be essential?

(9) What would you consider the most appropriate way to develop the concept, definitions and criteria further

(a) A study

(b) CARACAL discussions

(c) A CARACAL sub group

(d) other

ANNEX I: AN ILLUSTRATIVE EXAMPLE

At this early stage, it is not meaningful using a realistic example to depict how an essential use concept could potentially be integrated in REACH. While an abstract example is less tangible, at this stage it would not be appropriate to even remotely suggest a possible conclusion on what kind of uses could be seen as essential or not.

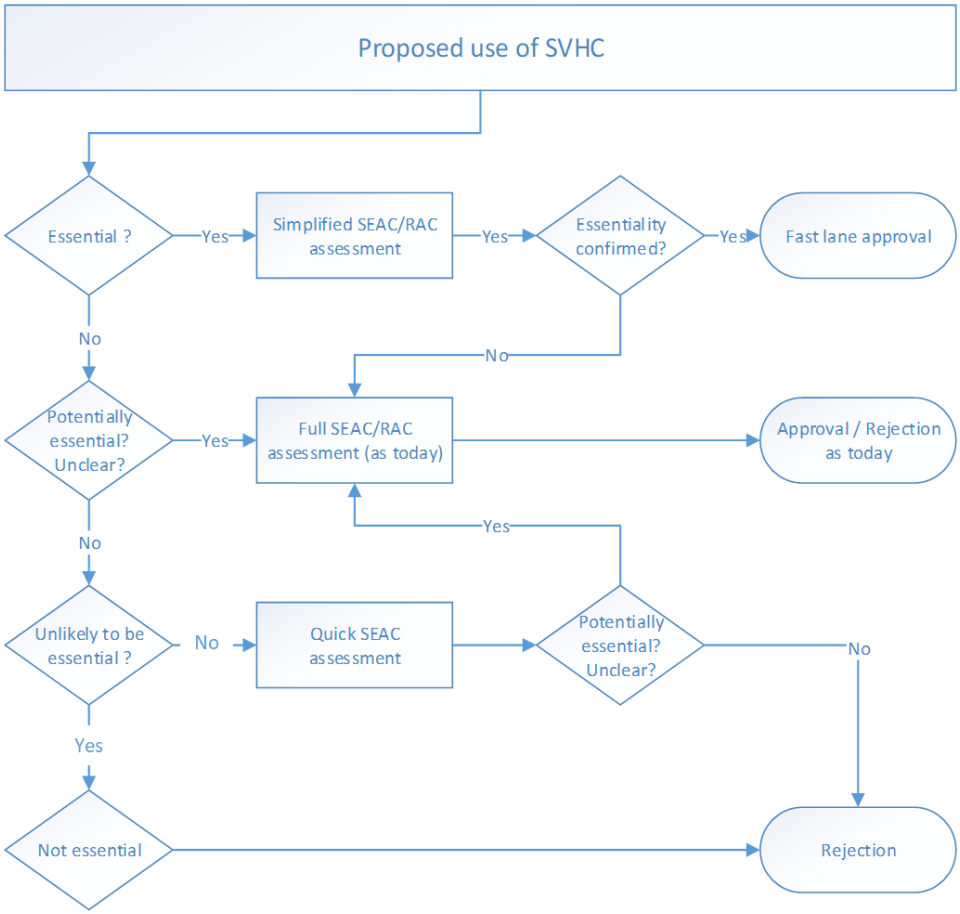
IMPORTANT: The flowchart below is only one possible way to integrate an essential use concept in REACH procedure for authorisation. Its sole purpose is to visualise one potential option so as to make the concept outlined above more tangible. It shall under no circumstances be understood as a proposal or a fully developed idea. As outlined above it will only be meaningful to develop specific ideas once the process is sufficiently advanced.

The example flowchart on the authorisation process suggests three basic process steps:

(1) Political pre-decision on essentiality (or the likelihood of essentiality)

(2) SEAC/RAC assessment (potentially simplified if essential or likely to be essential)

(3) Approval/Rejection by the REACH Committee



ANNEX II POSSIBLE QUESTIONS TO DETERMINE (NON-)ESSENTIALITY (NON-EXHAUSTIVE AND ILLUSTRATIVE)

This Annex contains a random and non-exhaustive list of questions that could potentially be used to determine whether a use is necessary for health, safety or critical for the functioning of society.

It is important to note that the questions listed below do not necessarily have yes/no answers. They are only suitable to hint towards a certain direction but not to draw final conclusion. In particular where the question refers to sectors, it would still be necessary to look closer at the specific use.

Hinting towards essentiality

Is the use contributing to:

(1) sectors listed in the EU policy on critical infrastructures?

(2) other sectors considered politically relevant to achieve strategic objectives?

(3) national security?[24]

(4) other security needs (e.g. fire-fighting, emergency services)

(5) other sectors considered essential by society

(6) food security

(7) healthcare

(8) innovation

(9)

(10) …

[24] Note that uses related to defence may already benefit from an exemption under REACH