

Commission Communication on Essential Use

Briefing (Vol 1.1)

On 22 April 2024 the European Commission published the Communication 'Guiding criteria and principles for the essential use concept in EU legislation dealing with chemicals' (C(2024) 1995 final), a key deliverable under the Chemical Strategy for Sustainability (COM(2020) 667).

The Commission indeed committed to: "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"

This briefing proposes an explanation and external assessment of the criteria set out by the Commission. It has several purposes:

- 1. presenting the objective and components of the communication (see questions 1 & 2),
- 2. offering an interpretation of its key components (questions 3 6),
- 3. establishing a starting point for future work to ensure the uptake of essential use considerations in legislation (questions 7 9), and
- 4. from this, deriving specific policy demands (question 10).



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1. What is the purpose of the communication?

The Communication introduces criteria and principles to determine 'essential uses' of the most harmful chemical substances. This is intended to guide the assessment of whether the use of the most harmful substances can be justified in certain circumstances, to inform risk management decisions taken in the context of EU legislation dealing with chemicals.

The Communication does not mention the possibility to use the criteria in the implementation of existing law. Rather, it aims to provide a blueprint for the harmonised integration of essential use considerations in future legislative proposals (see Questions 6 and 7).

2. What are key criteria and principles?

In the views of the Commission, a use of a most harmful substance is essential for society if the following two criteria are met (p. 4):

1) that use is necessary for health or safety or is critical for the functioning of society,

<u>and</u>

2) there are no acceptable alternatives.

But essential uses which fulfil both criteria by no means should be marketed without any limitations. Rather "conditions should normally be set" (p. 6) "to minimise exposure to human and animals and the emissions to the environment during production, use, end-of-life and recycling, including conditions limiting the quantity of the substance in the use" (p. 22). Information requirements can also be incurred e.g. on "the use in the supply chain and to consumers and waste operators" (p. 22).

In addition, acknowledging the dynamic nature of what society considers essential or acceptable, "it is in most cases useful to set a time-limit and review essential use permits" (p. 6).

Some definitions as well as lists of non-exhaustive examples are provided (p. 5), including:

- **Most harmful substances** (MHS): Substances that have one or more of specifically listed hazard properties (such as carcinogenicity, reproductive/developmental toxicity, endocrine disruption, certain persistent and mobile chemicals, see Question 6 for more details).
- The technical function of the MHS in the use is **necessary for health or safety** if e.g. in order to prevent, monitor or treat illness and similar health conditions, sustain basic conditions for human or animal life and health (secure sufficient and safe food, access to clean water and air etc.) or manage health crises and emergencies.
- The technical function of the MHS in the use is critical for the functioning of society if e.g. in order to provide resources or services that must remain in service for society to function (e.g. ensure the supply of energy and critical raw materials or resilience to supply disruption, strategic autonomy), manage societal risks and impacts from natural crises and disasters (such as floods, fires, earthquakes), protect and restore the natural environment, perform scientific research and development (such as laboratory analysis, measurements and testing), protect cultural heritage (specifical focus on conservation).

For the definition of 'acceptable alternative', see question 4 below.



3. What is a use?

The Communication defines use of a substance as "any processing, formulation, consumption, storage, keeping, treatment, filling into containers, transfer from one container to another, mixing, production of an article or any other utilisation" (p. 6). To determine essentiality of that use, "it will be necessary to take into account the context of the use provided by the final product and the service or purpose that it fulfils for society and the users (e.g. consumers)" (p. 7).

In the Annex (p. 9), the Communications sets out that "[d]etermining the particular use of a chemical and its scope are the starting points of any assessment based on the following elements:"

- characteristics of the use and the process which the **particular use** is serving (e.g. what is the use and how is it carried out and by whom),
- the **technical function provided** by the substance in the use and
- the context of the use.

The context analysis comprises an assessment of "the final product(s) or service(s) resulting from the use of the substance". Service is defined as the "purpose(s) that the final product fulfils for its user or receiver (an activity or function, not a physical object)" (p. 6).

Accordingly, the Communication follows a broad understanding of use, reflecting concepts developed in the literature. Taking the example of Bisphenol-A (BPA) in thermal paper: in this use case, acting as a chemical developer is the **technical function** of BPA. Creating a printed image could frame the **particular use** that BPA is serving. Providing a record of sale to a consumer constitutes the **societal service (context).**

Use of a MHS may be acceptable only if it is essential on those three functional levels. That requires to ask 3 main questions: 1) How critical is the performance for the application? 2) How critical is the application for the societal service? and 3) How critical is the societal service?

For each step of the assessment, the existence of an alternative will have a considerable role to play in the conclusion on the criticality. In other words: if there is an alternative at any level of function, a use cannot be deemed essential (see Question 4).

4. What is an acceptable alternative?

Criterion 2 of the introduced concept reads "there are no acceptable alternatives". The Communication defines 'acceptable alternative' (p. 4) as "substances, materials, technologies, processes or products, which, from a societal point of view:

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¹ Tickner J. et al. "Advancing Safer Alternatives through Functional substitution", Environmental Science & Technology, 2015.



i. are capable of providing the function and the level of performance that society can accept as sufficiently delivering the expected service

AND

ii. are safer (their overall chemical risks to human or animal health and the environment throughout the whole life cycle are lower in comparison to the most harmful substance)."

The Communication confirms for Criterion 2 i. that the "assessment should not only consider possible alternatives with the same level of performance but also any alternative with a function and a level of performance that society can accept as sufficiently delivering the expected service" (p. 19). MHS use can therefore be non-essential also when the alternatives imply loss of performance.

Criterion 2 ii. deviates from the original wording of the role model for essential use, i.e. the Montreal Protocol, which reads: "There are no available technically and economically feasible alternatives or substitutes that are acceptable from the standpoint of environment and health."

While not explicitly explaining and justifying this deviation,² the Communication refers to the fact that legislation "*normally*" provides for schemes to assess acceptability of alternatives, with guidance for technical and/or economic feasibility assessment specified "*for most pieces of legislation*" (p. 4). It provides alternatives assessment in the context of REACH authorisation as example.

The deviation raises the question whether the Communication falls short of the level of protection targeted by the Montreal Protocol.

Drawing from experience of current chemical policy implementation, (perceived) lack of alternatives is one major barrier for stricter regulation on chemicals, e.g. in the contexts of REACH restriction and authorisation. NGOs try to increase the visibility of available alternatives to show that MHS uses are not essential. Adding the 'acceptable from the standpoint of environment and health' criterion, on the one hand, would add another hurdle to establish that alternatives are available. Depending on the interpretation of the terms (e.g. environment could easily be framed as 'environmental sustainability') this could dramatically increase the burden of proofing viability of an alternative.

On the other hand, alternatives obviously must not increase the chemical risk. Indeed, the Commission's concept clearly addresses this aspect by stating that acceptable alternatives need to be safer. It does however do so only at the level of the definition of terms, not at the level of the criteria. A preferable formulation for criterion 2 that does not interfere with existing assessments but is still more protective could read there are no acceptable alternatives which result in reduced overall risks to human health and the environment.

5. Will the criteria support the phase-out of MHS?

The primary objective of the essential use concept is clear; the first in a list of principles reads (p. 6): "[t]he aim of the concept is to increase the protection of health and environment by accelerating the phase-out of the uses of the most harmful substance that are non-essential and, where they are essential, to provide time for their substitution" (emphasis added).

² The Communication contends in general terms that "the essential use criteria used in the Montreal Protocol are not general enough to be workable in all relevant EU legislation dealing with chemicals", p. 9.



Whether the criteria will accelerate the phase-out of MHS, have little to no effect or even slow down progress, will however depend on how they are implemented.

Employing the criteria could facilitate the identification of uses normally not deemed essential, such as those "relating to convenience, leisure, decoration or luxury" (p. 13). Also, for the less clear-cut cases, the broader perspective of alternatives available for the societal service of a MHS use could help with identifying non-essential uses.

However, the Communication suggests that "[t]he scope of the use should be defined in a sufficiently narrow way so that lack of alternatives can be demonstrated" (p. 10). Besides, the criteria shall as well inform the assessment of uses to be exempted from a ban. This will open the door to all sorts of claims for companies that are naturally convinced that the MHS use on which they base their business models must be essential. Alternatives assessment at the technical level of substance use may end up in exhausting fights about acceptable performance levels.

ClientEarth has proposed balanced guidance to interpret and implement essential use, aimed at ensuring effective phase-out of MHS.

6. Do the criteria deliver on the CSS commitments?

The Chemical Strategy for Sustainability (CSS, <u>COM(2020) 667</u>) finds that "existing EU chemicals policy must evolve and respond more rapidly and effectively to the challenges posed by hazardous chemicals" and that this has to involve "phasing out the most harmful ones for non-essential societal use, in particular in consumer products" (CSS, p. 2). From this, commitments are derived relating to the essential use criteria as such and to the implementation thereof.

On the criteria, the Commission committed to (CSS, p. 10) "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." Complementing this, the Annex to the CSS lists "[k]ey actions to be taken by the Commission staff", including "[d]efine criteria for essential uses, taking into account the definition of the Montreal Protocol". The indicative timing foreseen for this deliverable was 2021-22. As for Criterion 2 on alternatives, the Communication on essential use omits the precision that alternatives have to be "acceptable from the standpoint of environment and health", but at least provides that alternatives have to be safer (see Question 4).

As regards the scope of MHS, the CSS defines those as CMRs, EDCs and chemicals that are "persistent and bioaccumulative" as well as those affecting the immune, neurological or respiratory systems and chemicals toxic to a specific organ.

The Communication on essential use indeed applies to all of these substance groups – provided they meet the CLP criteria according to classifications done by the companies of every substance form they are pacing on the market.⁵ It limits the scope to those substances for which available scientific evidence clearly establishes these most harmful properties (Category 1 or 1A/1B classifications), though. This

³ A document category (e.g. Commission Recommendation or Communication) was not defined.

⁴ Other than that, in the CSS the Commission committed to take into account the Montreal Protocol, which it obviously did.

⁵ It means harmonised classification by authorities is not a prerequisite.



prevents a more precautionary approach also targeting chemicals based on available evidence suspected to be most harmful.

However, by mentioning persistent, mobile and toxic/very persistent and mobile (PMT/vPvM) chemicals subject to further assessment, and chemicals hazardous to the ozone layer, the Communication goes beyond what the CSS has promised.

In summary, apart from the delay, the Communication fulfils the commitments of the CSS.

7. Do the criteria have a legal effect?

To answer this question, both the form and the substance of the Commission's Communication are relevant.

As for the form, the document at hand comes as a Communication.⁶ It has no direct legal effect per se, because it does not belong to the Union acts that have a legally binding effect, as specified under Article 288 TFEU.

As for the substance, to determine the legal effects of EU documents, the courts refer to objective criteria, "such as the content of that act, taking into account, as appropriate, the context in which it was adopted and the powers of the institution which adopted the act". The Communication itself clarifies that the "concept of essential use only has legal effect when introduced into specific legislation" (p. 2). The Communication furthermore does not expressly encourage actors to use the criteria in the interpretation of existing laws. It finally makes explicit that it "does not have the purpose or effect of interpreting any legal act currently in force" (p. 1). The status of this communication is therefore different from e.g. ECHA Guidelines which are likewise not legally binding but precisely intended to inform the interpretation of legal provisions in REACH and CLP. In other areas such as competition policy, the Commission has used communications to spell out its understanding of key legal concepts and provide recommendations as to their practical implementation. Also taking into account the context of the Communication, the CSS did not indicate that these criteria as such should be binding in nature.

Companies relying on the Communication therefore are taking a risk. Existing 'EU legislation dealing with chemicals' already refers to essential uses. This is true, for instance, for Commission Delegated

⁶ It is relevant to note the document number which reads C(2024) 1995 final. According to the <u>Register of Commission Documents</u>, category C stands for "Commission autonomous acts, including delegated and implementing acts, other types of decisions etc" – i.e. documents with a binding nature. Communications, in contrast, belong to category COM. Hence the document number for the essential use Communication should read COM(2024) 1995.

⁷ Court of Justice Judgement of 20 February 2018, Kingdom of Belgium v Commission, C-16/16 P, ECLI:EU:C:2018:79, paragraph 32 et seq.

⁸ See however <u>questions</u> and <u>answers</u> accompanying the Communication, question "7. How will this initiative benefit businesses?" and the answer: "The Communication will benefit companies and businesses by providing predictability in terms of types of chemical substances and uses which shall be targeted for phase-out by future regulatory processes, and which ones may continue to be used to fulfil societal needs, provided there are no alternatives available. Thereby it provides clear signals on where investment and substitution efforts shall be directed, and an investment horizon for maintaining or increasing production capacity in the EU, in particular to support the green and digital transition or strengthening defence capabilities, when technologies or products currently rely on the most harmful substances."

⁹ And may thus raise 'legitimate expectations' by industry, see EU General Court judgment of 11 May 2017, Deza v ECHA, T-115/15, EU:T:2017:329, paragraph 137 and the case-law cited. Similar considerations apply to Commission Communications, see Court of Justice judgment of 20 March 1997, France v Commission, C-57/95, EU:C:1997:164, paragraphs 9 to 23.



Regulation (EU) 2023/2772 supplementing the Corporate Sustainability Reporting Directive ("non-essential societal use"). 10 Yet, this regulation does not define non-essential societal use, so one can expect that the Communication could be considered by producers and auditors to inform the interpretation of that provision. Nothing hinders companies from adapting their strategies and operations according to the criteria and principles, and invest in MHS uses they deem, in their reading of the Communication, essential. However, if future legislation would render these uses as non-essential, these companies could not invoke the Communication to avoid or reduce liability.

That being said, although the communication is not legally binding, it is capable of significant effects in practice. Notably, the fact that it is not legally binding does not prevent legislators from taking it into account when implementing the applicable legislation (see question 8).

8. Can the criteria be used in REACH implementation?

While the criteria do not exert any direct legal effects (Question 7) policymakers could still consider them for the implementation of existing EU policies on chemicals. It would depend on whether these policies allow for integration of the essential use rationale.

In the context of the current REACH authorisation and restriction regimes, technically there is nothing that prevents essential use considerations to guide regulatory decision-making by the Commission and Member States as well as scientific opinion-making by ECHA's Committee for Socio-economic Analysis 'SEAC' (see below). There is a general reluctance, even fear, to refer to a term that is considered too political to be integrated into REACH processes – intended as fundamentally objective, scientific and apolitical processes. But it is largely forgotten that considerations related to the societal value or understanding of chemicals and their uses are already today a big part of the opinion and decision making related to both REACH restrictions and authorisations. Integrating the essential use framework would mean rendering explicit what is already assessed today in an implicit manner. However, in order to further legitimise the concept, implementing legislation (comitology) should be considered and adopted to formalize essential use in these procedures (question 10).

Apart from the legal procedures, the concept could furthermore be used as a filter at political level, e.g. when prioritising activities listed on roadmaps.

In Authorisation

Identification of SVHCs is the first in a long list of procedural steps in the authorisation regime as specified in Title VII of REACH. Article 57 REACH defines (eco)toxicological criteria that substances must meet to qualify as SVHC. At this stage, essential use could help prioritizing substances for SVHC identification, i.e. those with mostly non-essential uses or for which alternatives are available.¹¹

Some procedural steps later, once a SVHC is placed on Annex XIV making the chemical subject to the authorisation requirement, companies cannot be prevented from applying for authorisation of SVHC

¹⁰ Annex I, ESRS E2 POLLUTION, Disclosure requirement, para 15: "The undertaking shall indicate, with regard to its own operations and its upstream and downstream value chain, whether and how its policies address the following areas where material: (...) (b) substituting and minimising the use of substances of concern, and phasing out substances of very high concern, in particular for **non-essential societal use** and in consumer products;" (...). (emphasis added).

¹¹ Since the Communication is not legally binding, it does not prevent extending the substance scope of essential use considerations to few SVHCs which are not covered by the MHS term, i.e. potentially substances of 'equivalent level of concern' identified under Article 57(f) REACH.



uses, including those that are clearly non-essential (e.g. decorative chrome plating). Moreover, the Commission is obliged to grant authorisation under Article 60(2) for the – very rare – cases where applicants can show that any risk linked to their desired use is "adequately controlled".

For most SVHCs, this so-called 'adequate control route' is however not available. 13 Consequently, authorisations for the majority of SVHCs are handled through the so-called 'socio-economic route'. There, according to Article 60(4), "an authorisation may only be granted if it is shown that socio-economic benefits outweigh the risk to human health or the environment arising from the use of the substance and if there are no suitable alternative substances or technologies". The socio-economic route thus comprises two assessment parts, one being linked to socio-economic analysis (SEA) and another linked to the analysis of alternatives (AoA).

(1) As regards SEA, i.e. the assessment whether the benefits of continued use of a SVHC outweigh the risks, employing essential use could prevent authorisation decisions based purely on economic factors. It would thereby clarify the societal scope already embedded in Annex XVI of REACH on socio-economic analysis (see the box below), by implying an assessment of the necessity of the use for health and safety or of the criticality of the use for the functioning of society. As a result, SEAC could simply flag which uses applied for it considers essential or not, thereby providing important context for the eventual decision-making by the Commission (and Member States).

Socio-economic analysis (SEA) in Annex XVI¹⁵

Socio-economic considerations are an integral part in the assessment of REACH applications for authorisation. Also, when restrictions are prepared, following Article 68(1), the socio-economic impact needs to be taken into account. Providing guidance as to how to address such concerns, Annex XVI of REACH contains non-exhaustive, broad and indicative "information that may be addressed by those submitting a socio-economic analysis", while stating that the level of detail and scope is ultimately the responsibility of the actor preparing the SEA. Annex XVI covers diverse factors, yet its focus is particularly broad – on competitors, market, sectors, alternative providers, consumers and workforce. Essentially, it endorses a societal perspective, as is also confirmed by Annex XV.¹⁶

(2) As regards AoA, as is also summarised by the Communication (p. 20), there is case law interpreting the assessment if alternatives are available, thus framing the application of essential use. Respecting this jurisprudence, the concept still adds value by explicitly stating that AoA "should not only consider possible alternatives with the same level of performance", i.e. but also those with lower levels of performance (see already Question 4). This hints at a common strategy put forth by applicants for authorisation, and then unfortunately endorsed by the majority of SEAC members, to justify that continued use of the SVHC in question – hence, business as usual – is warranted: because no other

¹² See ECHA's "Applications for authorisation under REACH" briefing.

¹³ Because the substances do not fit into the standard risk assessment rationale, e.g. due to lack of effect thresholds, see Article 60(3) REACH.

¹⁴ European Commission, Directorate-General for Environment, Bougas, K., Flexman, K., Keyte, I., et al., Supporting the Commission in developing an essential use concept: final report, 2023, https://data.europa.eu/doi/10.2779/529713, 136.

¹⁵ A more detailed analysis can be found here: <u>Socio-economic assessment and REACH authorisation</u> (clientearth.org).

¹⁶ See Section 3 of that Annex: "The socio-economic impacts of the proposed restriction may be analysed with reference to Annex XVI. To this end, the net benefits to human health and the environment of the proposed restriction may be compared to its net costs to manufacturers, importers, downstream users, distributors, consumers and **society as a whole**" (emphasis added).



level of performance than the level provided by the SVHC is acceptable. This practice has been openly criticized, notably in recent literature, as well as by the European Parliament and the EU Court of Justice. Already under the existing mandate, SEAC could properly assess lower performance alternatives and force applicants to provide evidence why those should not be acceptable; in practice, this is however not the case. Again, SEAC could flag availability of acceptable alternatives, thereby providing highly relevant context for the authorisation decision.

As regards the decision-making in the context of authorisation, in practice the Commission always has granted authorisation when the applicant could establish lack of suitable alternatives, in the sense of not yet technically or economically implementable for that specific applicant. Maintaining this way of implementing the 'socio-economic route' would mean that even when essential use could help rule-out applicants' push for decisions based purely on economic factors and could increase visibility of acceptable alternatives, the same applicants could still get what they want by playing the 'no suitable alterative' card – a claim that the Commission has been sanctioned by the Court on multiple occasions for supporting too easily.

From a legal point of view, however, the Commission has the mandate and discretion to not grant the authorisation applied for, even in the absence of alternatives, or if the benefits in terms of avoided costs for the applicant outweigh the risks. 18 Essential use could thus add value to the authorisation scheme and strengthen the rationale behind related decisions, if the Commission were to adapt its decision-making practice.

In Restriction

In REACH restrictions, the concept can be used to filter non-essential uses to be banned as a priority or, conversely, as the rationale to identify necessary derogations. Hence, it can guide the preparation of the restriction dossier as well as the Commission decision pursuant to Article 73(1) REACH. One could argue that, already today, policymakers, while not explicitly referring to the concept, have essential uses in mind when framing the scope of a restriction, in particular when the proposed restriction has a broad scope (e.g. in the case of the uPFAS restriction initiative). In the microplastics restriction initiative, essential use could have helped filter out uses for which from the outset it was clear that they are not critical and that alternatives are available (e.g. cosmetics). Such procedural 'short-cuts' would have enabled significant resource savings, both on the part of authorities but also on the part of stakeholders involved.

In addition, essential use can also guide opinion-making by SEAC in the way that was outlined for the authorisation context above.

9. What do we learn about the REACH reform?

Essential use was supposed to become a cornerstone of the revised REACH Regulation. The impact assessment in the run-up to the REACH reform looked into options how to introduce the concept into the

¹⁷ See e.g. this minority position on an application for authorisation of CrVI uses by SRG Global: "However, the applicant did not provide information (customer survey, market research,...) regarding the consequences if the performance in terms of color (either specific color difference for alternative coatings, or color stability) or touch is modified by the alternatives. Issues in terms of final customer acceptance are only claimed and not demonstrated". (emphasis added).

¹⁸ See Sentence 2 of Article 60(4) REACH which requires the Commission to "*take into account*" the Committee opinions and "*consider*" some elements, including the information submitted by the applicants.



regulatory framework, 19 supported by a study done by consultants. The Communication on Essential Use does only indirectly comment on the REACH reform, in the context of alternatives assessment (p. 4):

"In most EU pieces of legislation, a technical and/or economic feasibility assessment is part of the assessment of alternatives: for example, in REACH, it is not sufficient to show the existence of an alternative in abstracto, in laboratory conditions or in exceptional conditions. The Annex shows some of these examples. The Commission does not intend to change existing references to a technical and/or economic feasibility assessment if it proposes to introduce the essential use concept in any such legislative area. The Commission will weigh up the appropriateness of such references to the legislative context when considering the introduction of the concept of essential use in any other areas".

It follows that the Commission, when proposing to introduce the essential use concept into legislation, "does not intend" to change existing references to technical and/or economic feasibility assessments. The quote seems rather clear that this rationale would in any case apply to a reform of REACH.²⁰

This statement is at least problematic as, if and once REACH reform discussions gain traction again, it could pave the way for an argument to keep current socio-economic assessment (SEA) procedures with essential use only being considered as an add-on.

In procedural terms, however, the decision to keep SEA has to be subject to an impact assessment thoroughly considering the available policy options. It is not for the Communication to pre-empt decisions to be taken by the future legislators; in particular as the current Commission did not consider itself capable of proposing a REACH revision or sharing details of the preferred options.

In material terms, in fact, the study supporting the Commission's impact assessment identified the full replacement of the SEA route by essential use considerations as best available option to reform REACH authorisation.21

10. What are ClientEarth's demands?

Following the above considerations, ClientEarth asks for a tiered 3 stages approach of employing essential use in REACH, comprising measures that range from ad hoc activities to, eventually, the fullyfledged operationalisation of essential use as part of a REACH reform:

1. Get started! - The essential use concept could be implemented already today in REACH restriction and authorisation to the benefit of ensuring a high level of protection (Question 8). We therefore ask the Commission to urgently assess options to support the uptake of the concept in existing procedures and opinion-making frameworks. First step should be a more comprehensive analysis of the extent that existing documents and procedures already reflect the essential use rationale and what targeted complements could facilitate the concept's uptake - this briefing could be used as a starting point for this exercise. The assessment has to be done in cooperation with the Member States and ECHA, including the SEAC and the Member State Committee. Those options should comprise

¹⁹ According to the Impact Assessment submitted to the Regulatory Scrutiny Board it scrutinizes an "option to introduce an essential use concept to grant authorisations or derogations from restrictions".

²⁰ In contrast, it is far from clear what it means for legislation other REACH.

²¹ See Sub-option D in European Commission 2023 (note 14), 169.



- updates of Guidance documents and templates for analysis of alternatives, emphasizing the
 acceptability of lower performance alternatives and SEAC's role to request relevant evidence
 from the applicant, and
- updates of the Guidance documents and templates aimed at strengthening qualitative arguments in socio-economic analyses and emphasizing the overall societal context of SEA – in line with the REACH legal text,²²
- the provision of templates for restriction dossier submitters for a structured essentiality
 assessment (checklists for assessments of necessity and criticality, as well as alternatives'
 availability), and
- an overhauled internal decision-making framework for the Commission that prioritizes the primary goal of REACH to ensure a high level of protection,²³ even in the absence of alternatives, or if the benefits in terms of avoided costs for the applicant for authorisation outweigh the risks.
- 2. Enhance legal clarity! The current REACH legal text does not mention essential use. This may hinder authorities and SEAC from getting started, due to, for example, concerns that decisions taking into account essentiality considerations may not stand up in court or due to lack of political will to proactively employ the concept. To address these concerns, and to ensure consistency in essential use application and thus predictability for all stakeholders, we ask the Commission and Member States to assess available options²⁴ for the adoption of implementing legislation aimed at providing a clear legal basis for essential use considerations in the current legal framework. The latter could be achieved by
 - amending Annex XV Section 3 on Dossiers for restriction proposals and Annex XVI on SEA,
 - or by adopting stand-alone implementing legislation stipulating how essential use may or shall guide decisions in the context of relevant REACH processes.
- 3. **Essential Use-fuelled REACH reform!** The CSS states "existing EU chemicals policy must evolve and respond more rapidly and effectively to the challenges posed by hazardous chemicals", 25 while introducing the essential use concept as cornerstone of the revised framework. All political players and stakeholders have to work towards "a revision of the REACH Regulation in the most targeted way possible, limited to achieving the objectives of this Strategy" (see also Questions 6 and 8). 26 Accordingly, REACH should be revised to the extent that
 - essential use becomes the central mechanism to determine which substance uses to regulate in restrictions and authorisations and which exemptions from such rules may be temporarily justified, and that
 - essential use considerations fully replace SEA.

Stages 1 and 2 could be launched immediately, with implementing legislation being adopted – depending on the complexity – within months. In parallel, the way for a REACH reform delivering on the

²⁶ CSS, 24.

²² Socio-economic assessment and REACH authorisation (clientearth.org).

²³ See e.g. judgment of 7 March 2013, Rütgers Germany and Others v ECHA, T-94/10, EU:T:2013:107, para. 134.

²⁴ The study supporting the Commission's impact assessment looks into available options and their feasibility, see European Commission 2023 (note 14), 169.

²⁵ CSS, 2.



CSS commitments needs to be paved. ClientEarth has made detailed proposals how to introduce essential use in the context of REACH restriction and authorisation.²⁷

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²⁷ See our REACH reform <u>Demands #3: A systemic approach to risk management by authorities</u> and <u>#4: A coherent approach to exemptions from risk management</u>, as well as the briefing <u>Essential Use & EU law</u>.