POSITION PAPER

February 2022

THE 'ESSENTIAL USE' CONCEPT

KEY MESSAGES

1 The 'Essential Use' concept (EUC) represents a departure from the current risk-based regulatory approach and poses a number of challenges and potential risks such as unclear definitions, substitution by less sustainable alternatives or delay in regulatory decisions.

2 It is therefore paramount to ensure the possible integration of the EUC in a way that can enhance the system's ability to regulate harmful substances without putting breaks on much needed innovation and competitiveness of industry.

3 The mere presence of a hazardous substance in a process or product is not a sufficient reason to apply the "essentiality" assessment. The EUC could therefore be a valid solution only if applied in a targeted manner, i.e., in case of proven risks to the health and environment, difficulties in managing these risks and if no acceptable alternatives or substitutes exist.

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1. INTRODUCTION

Chemicals are key components of materials used in every-day life, from the food we eat to the medicines we take, from the cosmetics we apply to the devices we use or the clothes we wear. Chemical processes and products are present in all industrial ecosystems and are as such essential to the green and digital transitions of the EU's economy. In light of the EU's ambition to become the first climate neutral continent by 2050, it is important to note that chemicals are also integral components of materials used for renewable energy production (e.g., wind turbines, solar panels). Naturally, all technological advancements needed to deliver on the ambitious European Green Deal objectives will thus be relying on chemicals in some shape or form.

The Chemicals Strategy for Sustainability (CSS) recognises the crucial role of chemicals for businesses and the society at large and aims at ensuring that all hazardous substances are used safely. With this objective, the Commission is currently assessing different aspects of the REACH Regulation to take a more informed decision on the revision of the Regulation itself.

The safe and sustainable use of chemicals is already enshrined in the existing legislative framework. With the REACH Regulation and its current authorisation / restriction process, the EU has one of the most sophisticated chemical legislations globally. In the context of the upcoming revision aiming to improve the decision-making, it is paramount to ensure the possible integration of the "'Essential Use' concept" (EUC) in a way that can enhance the system's ability to regulate harmful substances without putting breaks on much needed innovation and competitiveness of industry.

This paper aims to inform the European Commission's work on the EUC for the assessment and use of chemicals. The broad spectrum of industries and value chains, which strongly depend on the availability of chemicals, is particularly interested in this debate as their activities could be heavily impacted by the definition of what is going to be considered "essential".

2. THE 'ESSENTIAL USE' CONCEPT

Background

The essential use concept was originally established within the legal framework of the Montreal Protocol for a very homogeneous group of substances with proven toxic and very environmentally damaging properties leading to unacceptable risks. In particular, the international agreement conceded exemptions for essential uses of substances depleting the ozone layer if:

(i) It is necessary for the health and safety – or is critical for the functioning – of society (encompassing cultural and intellectual aspects); AND
(ii) There are no available technically and economically feasible alternatives or substitutes that are acceptable from the standpoint of environment and health.

According to the Montreal Protocol, the production and consumption of controlled substances for essential uses is permitted only if:

(i) all economically feasible steps have been taken to minimise the essential use and any associated emission of the controlled substance and
(ii) the controlled substance is not available in sufficient quantity and quality from the existing stocks of banked or recycled controlled substances.

The European Commission's approach

Whilst the Montreal Protocol has a narrow scope and addresses unacceptable risks (not simply hazards), the European Commission intends to take a more precautionary approach (no longer on an ad hoc basis) and apply the "'Essential Use' concept" on a hazard basis, i.e., all 'most harmful' chemicals and ban their consumer and professional uses, except essential ones, regardless of whether they actually present a risk.

In other words, the European Commission is expected to implement the concept in the context of the exemptions from restrictions (following Art. 68 of REACH) to only admit those uses of substances that are needed for the safety and functioning of society independent of their actual risk. The decisive factor would therefore be the hazardous properties of the individual substances or the substance group.

How to define "essential use"?

The definition of what the term "essential use" could mean, or which uses are "essential" to society, is a difficult exercise. It inevitably leaves the door open to many different interpretations, which sometimes can be linked to societal choices considerations. Also, from a practical point of view, it is difficult to define ex-ante what is deemed to be essential today and what might become essential later on. It is safe to assume that we cannot know definitively on which technologies the progress of our society will be relying on decades from now.

The essential use definition must not be a barrier to innovation. Research and development need transparent and understandable regulations. It must be ensured that a definition of essential use defined today does not restrict emerging and future technologies, incorporating changing scientific and technological developments and considering availability of substitutes.

The difficulty to define clearly the 'Essential Use' concept, e.g., through unambiguous criteria, could lead to unclear and sometimes arbitrary decisions in regulating

substances, which could encourage EU companies to invest into research & innovation outside of the European Union. It could also considerably reduce the availability of substances on the EU market which can have a negative impact on the innovative capacity of Europe's industry in all sectors.

The criteria for 'Essential Use' should be broad without excluding entire industry sectors and assessed specifically for substance by substance and use. Besides the functionality and wellbeing of the society, societal and cultural aspects should be considered as well as sustainability criteria. In addition, the aspect of safe use should be considered in this new concept.

Potential risks

The automatic application of the EUC based on hazard classifications could lead to the possible substitution of products by less sustainable, less performant or less durable materials. How so? With this concept, the market would be pushed towards using alternatives that may be less sustainable (environmental impact through e.g., higher lifecycle CO_2 emissions, an increasing amount of waste or lack of recyclability) and thus lead to a substitution that would be regrettable from a broader sustainability perspective and potentially in conflict with the EU Green Deal (e.g., lead in bearings & lead-acid batteries, use of fluoropolymers for heat and abrasion resistant non-metallic components in machinery, cobalt in hydrodesulfurization catalysts).

The question is, can the 'Essential Use' concept really work in practice? The Chemical Strategy envisions to streamline, facilitate and speed-up current processes. Contrary to the good intentions of improving the efficiency and speed of authorisations / restrictions, there is a risk of delaying regulatory decisions, thus undermining the very objective of the CSS. The wide application of the EUC to all substances with certain hazardous properties would lead to the need for an assessment of the different uses of all these substances. Considering the different applications of each substance used for many different applications, the regulatory process will be delayed as requiring a strenuous and granular "essentiality" assessment per each and every substance and its use. The impact of this on the regulatory process and its length cannot be underestimated and the effects on regulatory efficiency necessitate a realistic assessment of applying the EUC, carefully examining all the hurdles this process would encounter.

However, these delays are unjustified as there are products which can be safely used and recycled regardless of the toxicity profile of the substance. If the EUC is introduced in the way envisaged in the CSS, the already limited regulatory resources would therefore be deployed to assess essentiality of uses and would not be dedicated in a more focused manner to address risk in consumer uses. Hence, the resource issues identified in the REACH authorisation/restriction process would only become worse.

Finally, the international competitiveness of EU's industry could be severely hampered. An unfounded ban of the use of a hazardous substance means reducing the technological toolkit available to European manufacturers. This would lead to a substantial performance gap between products manufactured in Europe and the ones manufactured outside the EU, thus reducing the competitiveness of the former on the global market. In addition, an essential use exemption/derogation could result into

severely reduced volumes and therefore question the economically reasonable production within the EU. This would lead to higher vulnerability in case of disruptions of the supply chain.

3. THE WAY FORWARD

Implementing the EUC in a targeted manner

Considering the ongoing work of the European Commission and having in mind the risks of a broad application of the EUC, including unclear concepts and provisions in legislation, we recommend maintaining the exceptional approach of the Montreal Protocol. This means implementing the EUC in a targeted manner complementing the existing risk-based regulatory approach and therefore only in case of:

(1) unacceptable risks to health and environment,
(2) lack of adequate control measures and
(3) feasible alternatives with the same characteristics including the sustainable profile exist.

Alongside the current risk-based regulatory approach, which we consider to be the most appropriate, a EUC may be introduced in the REACH legislation complementing the existing restriction and authorisation processes which have the same objective – i.e., to ensure the safe use of the most harmful chemicals considering a high level of protection for human health and environment from adverse effects of chemicals.

Under the current regime every substance considered in the REACH authorisation or restriction processes undergoes a set of assessments, covering the risks, the mitigation measures, the possible alternatives available, the socio-economic impacts, etc. Many times, the current assessments already consider, the relevance of the uses for the substance concerned (even if not explicitly mentioned). Therefore, in addition to these assessments, we understand a new (formal) assessment step related to a EUC could be implemented to evaluate whether certain uses of a given substance fall under “essential” or ‘non-essential’, considering functionality, technical performance of alternatives and broader consequences if certain products are discontinued, etc., specifically from a sustainability perspective.

A robust definition of ‘essential use’

Uses to be considered “essential” to society should not be arbitrarily defined by regulators. Defining essentiality should be a matter societal debate and at the end political choice. It thus requires a proper assessment and discussion in a committee with representatives of the European institutions, industry as well as civil society and academia. This committee could be specifically empowered to assess essential use and give recommendations to the European Commission.

This discussion must be initiated before the concept is used for the first time and should continue to reflect the evolution of the “essentiality” definition: any EUC framework will need to account for the fact that essentiality is dynamic and subjective, and its impact

not limited to the EU. With this objective, the European Commission should establish a transparent and accountable dialogue, i.e., all relevant stakeholders should be involved, and the discussions should be science-based. What is more, the assessment process itself should also be reliable, transparent, and proportionate to the identified risk.

A Life Cycle Assessment

When assessing substitution alternatives, only a Life Cycle Assessment of products and substances can avoid regrettable substitutions. This means assessing environmental impacts associated with all the stages of a product's life, including raw material extraction, manufacturing, use and end-of-life management. To support this assessment, each industry sector could conduct an analysis of alternatives including impact of substitution, in preparation of a Regulatory Management Option Analysis (RMOA) used by the European Chemicals Agency (ECHA) to identify the most appropriate instrument to address a concern. The assessment must further be based on a case-by-case analysis of individual uses to avoid banning the use of a substance for an entire sector per se.

A major part of the assessment of essentiality shall be linked to the assessment of alternatives and their availability. However, considering that a systematic assessment of all possible alternatives per restricted substance is not realistic, it shall not be the only factor to conclude on the essentiality of a derogation.

All these elements combined can facilitate case-specific evaluations, streamline the scrutiny process and lead to better decision making, avoiding the concerns previously highlighted.

4. CONCLUSIONS

The EU business community stresses that the EUC represents a departure from the current risk-based regulatory approach and remains unconvinced of its added-value at this stage. Instead, the EUC could be used to complement the existing risk-based regulatory approach as needed.

The mere presence of a hazardous substance in a process or product should not automatically be associated with the default occurrence of a risk threatening human health or the environment: regardless of the toxicity profile of their components, products can be safely used, and recycled substances (including those with hazardous properties) can be key to sustainability.

The EUC – as envisaged by the Commission – is neither an appropriate, nor proportionate approach to ensure that all hazardous substances are safely used. On the contrary, it could be potentially detrimental to EU's sustainability efforts and research and innovation. The concept of essentiality should support, not block, the objectives of the Chemicals Strategy for Sustainability (CSS): ensuring a high level of protection for human health and the environment, whilst boosting innovation towards safe and sustainable chemical solutions.

We recommend to reconsider the need for the EUC and subsequently, its scope of application. The assessment should not be limited to a simple chemicals management perspective but needs to be better integrated with other policy objectives (including in the frame of the Green Deal) and seriously consider the risks of negative trade-offs.

Implementation of the EUC in a targeted manner would furthermore ensure that safe uses are not banned and that consumers can continue to benefit from these uses. By guaranteeing that the EUC will tackle actual risks, especially at consumer level, and not needlessly ban useful and safe articles, the regulatory approach will instil confidence and broad acceptance.

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