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From:	General Secretariat of the Council
To:	Ad hoc Working Party on One Substance One Assessment
Subject:	OSOA Package: Ad Hoc Working Party on One Substance One Assessment on 27 May 2024: Commission communication on essential uses of chemicals

With a view to the above AHWP, delegations will find attached the Commission communication on Guiding criteria and principles for the essential use concept in EU legislation dealing with chemicals.



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COMMUNICATION FROM THE COMMISSION

**Guiding criteria and principles for the essential use concept in EU legislation dealing
with chemicals**

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1. INTRODUCTION

The European Green Deal¹ announced the Commission's commitment to tackling climate change as well as pollution and biodiversity loss that are this generation's defining tasks. Most goods and technologies needed for the green transition rely on chemicals for a wide range of various functions. Chemicals are at the heart of Europe's major value chains, including consumer products, electronics, transport including batteries for electric vehicles, construction materials, and beyond.

At the same time, Europe has seen multiple examples where widely used chemicals have given rise to significant damage to health and environment. The widespread use of those chemicals, especially in industrial application, shows the complicated dilemmas we are faced with during the green and digital transition; the most harmful chemicals can be technically useful and versatile substances, some of which serving important performance functions in green technologies, but they are also highly problematic for health and safety and are found in humans and many environmental compartments all over the EU and worldwide at levels that will continue to increase if not addressed. Such dilemmas bring to the fore the 'essential use' concept that was announced in the Chemicals Strategy for Sustainability² to help achieve the aims of the zero pollution ambition for a toxic-free environment of the European Green Deal³.

To strengthen the resilience of the EU chemical industry and to enable it to play its role in the green transition, industry needs clarity and predictability, taking into account all these dimensions of the transition, in order to prioritise investments in innovation. The aim of this Communication is to elaborate on the concept and relevant criteria, and to guide its possible use, including in future chemicals legislation⁴. So far, no EU legislation contains a definition of essential uses of substances.

To inform the preparation of this Communication, a comprehensive consultation with a broad range of stakeholders from Member State authorities, industry, NGOs and academia was performed during spring 2022 in the form of a stakeholder workshop, surveys and targeted interviews⁵.

¹ COM(2019) 640 Final.

² COM(2020) 667 final.

³ COM(2021) 400.

⁴ The Communication is without prejudice to the Commission's right of initiative when presenting new legislative proposals. It does not have the purpose or effect of interpreting any legal act currently in force.

⁵ 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*, Publications Office of the European Union, 2023, <https://data.europa.eu/doi/10.2779/529713>.

1.1 Aim of the essential use concept

Hazardous chemicals can have serious effects and cause significant harm to human health and to the environment. To avoid and prevent that harm, but also costs for society resulting from diseases and remediation of environmental pollution, and to boost innovation for non-toxic material cycles and to achieve a clean circular economy, the Commission announced in the Chemicals Strategy for Sustainability that the most harmful substances⁶ should be phased-out in non-essential uses, in particular in consumer products, and minimised and substituted as far as possible in all uses. Certain uses of such substances may be essential for society, e.g. for climate change mitigation, digital transition, health protection, security and defence and thus necessary for the delivery of key EU policy objectives such as the European Green Deal and the digital transition. The Chemicals Strategy specifically 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’

The overall aim of the essential use concept is **to facilitate decision-making and increase regulatory efficiency to achieve a fast phase-out of the most harmful substances in non-essential uses while allowing uses still essential for society and continued availability of products serving human and animal health needs.** For uses that are essential for society, the concept can give companies certainty that substances otherwise targeted for phase-out can continue to be used to fulfil societal needs, until alternatives are available. The concept is a tool to help to **determine when a use of a most harmful substance is justified from a societal point of view.** Beyond the legislation setting the rules for access to the EU market, this concept can also be a tool to provide incentives under voluntary schemes such as sustainable finance and possibly other initiatives aiming to promote and reward the transition to safe and sustainable products and practices.

Implementation of the essential use concept should encourage companies to be proactive in phasing out the most harmful substances and to focus research and innovation on safe and sustainable alternatives⁷, promoting EU industry as a global frontrunner on the basis of the large EU internal market with a high consumer demand for safer, toxic-free products. The essential use concept can be applied equally to EU manufactured and imported products and thereby, maintain a level playing field for EU businesses.

The concept of essential use only has legal effect when introduced into specific legislation. Before incorporating it into a particular piece of legislation, careful consideration must be given to the feasibility of applying the concept, including the criterion of “acceptable alternatives”,

⁶ See definition in section 2.2.

⁷ Commission Recommendation of 8.12.2022 establishing a European assessment framework for ‘safe and sustainable by design’ chemicals and materials. C(2022) 8854 final.

having regard also to the objectives, needs and unique aspects of applicable sector-specific legislation. For example, in the case of medicinal products for human and veterinary use, medical devices and in vitro diagnostic medical devices, the strategic autonomy of the Union and availability of substances used in the manufacturing of products for health applications must be given due priority.

The essential use concept is designed to support industries in the EU as a valuable tool facilitating exemptions for uses clearly serving societal needs. This, in turn, can contribute to fostering an environment conducive to clean and sustainable manufacturing activities for goods within the EU.

1.2 Policy background

In 2019, the Council adopted the Conclusions “*Towards a Sustainable Chemicals Policy Strategy of the Union*” in which it calls on the Commission to develop an action plan to eliminate all non-essential uses of PFAS^{8,9}. In 2021, the Council adopted the conclusions “*Sustainable Chemicals Strategy of the Union: Time to Deliver*”¹⁰ in which it stresses that the concept of ‘essential uses’ is a key element in the implementation of the Chemicals Strategy for Sustainability that will receive priority attention in order to make it operational without undue delay.

In 2020, the European Parliament adopted a Resolution on the Chemicals Strategy for Sustainability¹¹ in which, amongst others, it calls on the Commission to define the concept of and criteria for the ‘essential use’ of hazardous chemicals, to provide a harmonised approach for regulatory measures on non-essential uses.

The Montreal Protocol¹², a multilateral environmental agreement, introduced an essential use concept already in 1992 and successfully phased-out chemicals that deplete the Earth’s ozone layer except for certain essential uses. The introduction of an essential use concept as a tool for chemicals risk management for a broader range of chemicals, in particular PFAS, has been increasingly discussed in academic and political circles¹³, and several scientific publications discuss how an essential use concept could be feasible for risk management^{14,15}.

⁸ Poly- and Perfluoroalkyl Substances

⁹ 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>

¹⁰ Council Conclusions of 15 March 2021 “Sustainable Chemicals Strategy of the Union: Time to Deliver”, <https://www.consilium.europa.eu/en/press/press-releases/2021/03/15/council-approves-conclusions-on-the-eu-chemicals-strategy-for-sustainability/>

¹¹ 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

¹² The Montreal Protocol on Substances that Deplete the Ozone Layer | Ozone Secretariat (unep.org)

¹³ Madrid Statement on Poly- and Perfluoroalkyl Substances (PFAS),

<https://ehp.niehs.nih.gov/doi/10.1289/ehp.1509934>

¹⁴ See, among others, Cousins, Ian T., et al. (2019). “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>)

2. THE ESSENTIAL USE CONCEPT

This section defines the essential use criteria, sets principles of the essential use concept and the main terms of the concept.

2.1 Criteria for essential use

A use of a most harmful substance is essential for society¹⁶ if the following two criteria are met:

- 1) that use is necessary for health or safety or is critical for the functioning of society,
and
- 2) there are no acceptable alternatives.

This Communication aims to provide clarity on those criteria as well as on how to make them implementable across legislation. The purpose is to communicate in simple terms their cumulative nature, while giving flexibility to consider specificities of individual pieces of legislation (e.g. as regards their notion of alternatives) where the concept could be applied.

An early frontrunner using the concept was the Montreal Protocol on substances that deplete the ozone layer, an international treaty to which the EU is a Party. The protocol defined the second criteria as: *‘there are no available technically and economically feasible alternatives or substitutes that are acceptable from the standpoint of environment and health’*.

As demonstrated in some examples in the Annex of this Communication, there is some variety in what terms are used to qualify the alternatives in EU law. 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. The following sections further explain and specify the criteria for essential use.

2.2 Terms underpinning the essential use concept

Table 1 below explains the main terms for the essential use concept in a non-exhaustive manner to provide direction for their application in relevant EU legislation as appropriate.

¹⁵ Cousins, Ian T., et al. (2021). “Finding essentiality feasible: common questions and misinterpretations concerning the “essential-use” concept.” Environmental Science: Processes & Impacts 23.06 (2021). (<https://doi.org/10.1039/D1EM00180A>)

¹⁶ Chemicals Strategy for Sustainability: Towards a Toxic-free Environment. COM(2020) 667 Final.

Table 1. Terms for the essential use concept.

Most harmful substances	A most harmful substance has one or more of the following hazard properties^{17,18,19}: • Carcinogenicity Cat. 1A and 1B • Germ cell mutagenicity Cat. 1A and 1B • Reproductive/developmental toxicity Cat. 1A and 1B • Endocrine disruption Cat. 1 (human health) • Endocrine disruption Cat. 1 (environment) • Respiratory sensitisation Cat. 1 • Specific target organ toxicity – repeated exposure (STOT-RE) Cat. 1, including immunotoxicity and neurotoxicity • Persistent, bioaccumulative and toxic/very persistent and very bioaccumulative (PBT/vPvB) • Persistent, mobile and toxic/very persistent and mobile (PMT/vPvM)²⁰ • Hazardous to the ozone layer Cat. 1²¹
Necessary for health or safety	The use of a most harmful substance is necessary for health or safety if the use and the technical function of the substance in that use are necessary in order to: • Prevent, monitor or treat illness and similar health conditions • Sustain basic conditions for human or animal life and health • Manage health crises and emergencies • Ensure personal safety • Ensure public safety These elements are described in Annex section III.b, table 2.
Critical for the functioning of society	The use of a most harmful substance is critical for the functioning of society if the use and the technical function of the substance in that use are critical 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)

¹⁷ Commission Recommendation of 8.12.2022 establishing a European assessment framework for ‘safe and sustainable by design’ chemicals and materials. C(2022) 8854 final.

¹⁸ Annex I of Regulation (EC) No 1272/2008 on the Classification, Labelling and Packaging of Substances and Mixtures.

¹⁹ Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures, COM(2022) 748 final.

²⁰ The inclusion of all PMT and vPvM in the subgroup of most harmful substances will be subject to further assessment.

²¹ The essential use concept is already relevant for substances hazardous to the ozone layer in accordance with the Montreal Protocol.

	• Manage societal risks and impacts from natural crises and disasters • Protect and restore the natural environment • Perform scientific research and development • Protect cultural heritage These elements are described in Annex section III.b, table 3.
Acceptable alternatives	Acceptable alternatives are substances, materials, technologies, processes or products, which, from a societal point of view: (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). Acceptability of alternatives takes a societal perspective. The notion of an “acceptable alternative” is normally defined with specific requirements in each piece of legislation, and for most pieces of legislation also includes a technical and/or economic feasibility assessment. These existing definitions (for example, technical and/or economic feasibility) should be considered if and when implementing the essential use concept in such areas.
Use of a substance	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.
Technical function of a substance (in the use)	The role that the substance fulfils when it is used, i.e., what it does in a process, mixture, or article. Technical functions are, for example, extraction solvent, degreasing agent, corrosion inhibitor, etc.
Final product	A product (substance on its own, a mixture, an article or a complex product) used by consumers, industrial or professional users. A most harmful substance can be used to produce the final product (while not being present in the final product itself) and/or it can be contained in the final product.
Service	The purpose(s) that the final product fulfils for its user or receiver (an activity or function, not a physical object).

2.3 Principles of the essential use concept

The core principles of the essential use concept are as follows:

- The 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.**
- The concept is intended to **determine** whether it is **essential for society** to use a most harmful substance with **a certain technical function**, with that substance either present in a final product or used to produce that product or provide a service. In all cases, 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). The use of a substance may be critical for the functioning of society or necessary for health or safety in one context but not in another (e.g. the need to use the substance providing a certain technical function in a lamp for surgery at a hospital may be different from the need to use it for a lamp at home or in a shop).
- The concept is **not intended to determine whether a certain substance, product, product group or service is *itself* essential for society, nor whether an individual consumer or company considers the use essential for them.**
- An **assessment of the use** and its context is needed. Specific uses of a most harmful substance within any sector could either fulfil the first criterion or not (e.g. use of a substance in an airplane engine providing a technical function necessary for safety vs. in an airplane seat or carpet with a technical function purely for decoration).
- **For a use to be proven essential, both criteria in section 2.1 must be met.** To bring **simplification and increase efficiency** of the assessment, if appropriate, uses under assessment may sometimes encompass broader product categories, and the assessment of criteria may be done in a structured manner (one-by-one).
- For uses proven essential, **conditions** should normally be set to **minimise the emissions and the exposure** of humans and the environment, in particular to avoid or minimise exposure of vulnerable groups such as children, pregnant women and elderly people, who are more sensitive to exposure of harmful chemicals.
- **The essentiality of a use is not static**, but evolves over time, in function of new information on hazards, new societal challenges and needs and new, innovative alternatives emerging. In balance between reasonable investment horizons, incentives to innovate in safer alternatives by way of prospects of later market penetration and the general aim of minimising use of most harmful substances, notably in consumer products, it is in most cases useful to set a time-limit and review essential use permits at the appropriate moment.
- To take account of this evolutive nature of essential uses, **substitution plans with commitments, timelines and steps envisaged towards transition to alternatives** could be required for uses of substances that are deemed essential and possible inclusion into research and innovation agendas could also be considered.

3. CONCLUSIONS

This Communication is meant to guide considerations on introducing the concept of essential use in EU legislation dealing with chemicals. When introducing the concept, the specificities of each instrument of legislation may need to be taken into account. Procedures, actors and bodies involved in the assessment and decision-making on essential uses need to be defined in those pieces of legislation.

By providing clarity for the Commission, for the other EU institutions participating in the adoption of legislation, as well as their addressees, this set of principles aims to provide a common framework that can improve predictability, consistency as well as allow the EU industry to rapidly deliver on the transition to zero pollution and a non-toxic environment as important parts of the broader EU policy agenda, notably the Green Deal transition.

ANNEX

I. OVERVIEW OF THE ESSENTIAL USE CONCEPT IN THE MONTREAL PROTOCOL

The Montreal Protocol is a global agreement which entered into force in 1989 to phase out uses of chemicals that deplete the Earth's ozone layer. This international treaty led to the successful phasing-out of most emissive uses of ozone depleting substances except for certain essential uses. It was acknowledged that, for a small fraction of uses, the phase-out would require more time and therefore, must be handled separately from the agreed phase-out schedule. In 1992, the Parties to the Montreal Protocol therefore decided²² that a use of a 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.

In addition, the Parties decided that production and consumption, if any, should be permitted only if all economically feasible steps have been taken to minimise the essential use and any associated emission of the substance; and the substance is not available in sufficient quantity and quality from existing stocks of banked or recycled substances.

Essential uses under the Montreal Protocol included substances in medicines, mainly asthma inhalers, laboratory and analytical uses, process agent uses, in firefighting and as solvents in aerospace applications. Different methods and conditions were used to minimise those essential uses. Yet, the essential use criteria in the Montreal Protocol are not further defined in the Protocol nor in any guidance.

The Montreal Protocol is often seen as one of the most successful multilateral environmental agreements. However, it is relevant to observe that it covers relatively few chemicals and is applicable at a global scale. Nevertheless, the essential use criteria used in the Montreal Protocol are not general enough to be workable in all relevant EU legislation dealing with chemicals.

II. WHAT IS THE PARTICULAR USE TO BE ASSESSED?

Determining the particular use of a chemical and its scope are the starting points of any assessment based on the following elements:

- **Main 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);

²² Decision IV/25 of the Parties to the Montreal Protocol: <https://ozone.unep.org/treaties/montreal-protocol/meetings/fourth-meeting-parties/decisions/decision-iv25-essential-uses>

- **Technical function** provided by the substance in the use – the role that the substance fulfils when it is used by itself, in a mixture, article or manufacturing process; e.g. processing aid, extraction solvent, degreasing agent, corrosion inhibitor, plasticiser, antioxidant, colourant and others.

The ECHA use descriptor system²³ for registration of substances under REACH may serve as a basis for description of technical functions but the use description may need to be supplemented by more detailed information, in particular on the technical characteristics and properties provided by the substance in the use (e.g. cleaning agent, having properties to lower the surface tension of liquids).

- **Context of the use**, in particular:
 - what is the **final product(s) or service(s) resulting from the use** of the substance;
 - the **need for the substance** in the use (e.g. whether the final product or process can deliver its service to the user without the substance);
 - the **need for the technical function of the final product** and how it is influenced by the *technical function of a substance* used to produce that product when determining if this use of the substance is necessary for health or safety, or critical for the functioning of society (e.g. whether there are different products on the market that can deliver the same service without the substance or without the technical function provided by the substance);
 - a set of **characteristics** (e.g. conditions, requirements, technical performance) **for the use and/or the final product, to frame the assessment of alternatives and the substitution** by an alternative (e.g. a set of requirements through which the service and function provided by the use of the substance can be delivered to the level needed and that is acceptable for the society). The scope of the use should be defined in a sufficiently narrow way so that lack of alternatives can be demonstrated;
 - details on how the use of the substance is carried out and of the various **activities/tasks** involved in the use, including exposure scenarios and the corresponding risk management measures and operational conditions (from human health and environment perspectives).

Once the scope of the particular use has been defined, it should be reflected in a **use description** with a sufficient level of detail to ascertain whether the essential use criteria are fulfilled. It is recommended that the use description contains the following elements:

- description of the use in relation to the final product or service resulting from the use;

²³ Appendix R.12.4. of the Guidance on Information Requirements and Chemical Safety Assessment Chapter R.12: Use description Version 3.0 - December 2015

- description of the use in relation to its necessity for health or safety or criticality for the functioning of society (e.g. the technical function and its need for the final product, including the context of the use);
- description of the use in relation to an analysis of alternatives (e.g. characteristics for the use and for the final product(s), framing the analysis of alternatives);
- description of the use in relation to exposure scenarios (e.g. certain parts of the use performed in a closed system), complemented by the corresponding measures to minimise the use, exposure and emissions from it.

III. ASSESSING IF A USE IS ESSENTIAL FOR SOCIETY

This section provides guidance on how to perform the assessment against the essential use criteria. When the concept is introduced in a particular piece of legislation, procedures, bodies and actors involved in the assessment and decision-making on essential uses need to be determined within that legislation. While the two criteria for essential use set out in section 2.1 should be assessed separately, they can be interdependent. The assessment of the necessity for health or safety or of the criticality for the functioning of society could influence the nature of the assessment of alternatives and vice versa. Setting of conditions for a use proven essential is described in section IV below.

a. Filtering out non-essential uses

The cumulative character of the essential use criteria and their structured assessment (criterion-by-criterion) offer the possibility at each step to filter out the uses not qualifying as essential, without the need for a full assessment of all the remaining criteria. Doing so allows to fully exploit the simplification and efficiency potential of this concept (see the overview figure below).

As a matter of principle, it is sufficient that the use is not fulfilling one of the two cumulative criteria to conclude that the use is non-essential. The uses failing an individual criterion can be filtered out and the further assessment of the remaining criterion can stop, which can bring efficiency gains and simplification. At the same time, the conclusion that the use is non-essential should be made with enough confidence. For example, if the first criterion assessed is the necessity for health or safety or criticality for the functioning of society and if it clearly fails, there is no need to undertake the assessment of the criterion on lack of alternatives, in order to conclude that the use is non-essential. Similarly, if the first criterion assessed is the lack of acceptable alternatives and it can be easily proven that acceptable alternatives exist for that particular use, there is no need to undertake the assessment of the criterion on necessity for health or safety or criticality for the functioning of society in order to conclude that the use is non-essential.

On the contrary, for a use to be proven essential, both criteria must be fulfilled and therefore, concluding that only one criterion is met is not sufficient to conclude that the use is essential for society.

ASSESSMENT OF THE USE

A structured assessment will help filtering out non-essential uses and provides simplification and efficiency by limiting the need for full assessment only to the uses that are necessary for health or safety or critical for the functioning of society. In certain cases, it may be more efficient to start with step 2 and then perform step 1.

Step 1 – Assessment of necessity for health or safety and criticality for the functioning of society

Questions to consider (section III.b):

- i. Is the technical function of the most harmful substance needed for the final product to deliver its service?
- ii. Does the use of the most harmful substance fulfil at least one element specified in tables 2 or 3 below so that it fulfills the criterion of being necessary for health or necessary for safety or critical for the functioning of society in the particular use?

(the answer to both questions must be 'yes')

NO

The use is *non-essential* for society. No further assessment needed.

YES

The use is necessary for health or safety or critical for the functioning of society.
Assessment of lack of alternatives is needed to determine if the use is essential for society.

Step 2 – Alternatives assessment

Questions to consider (section III.c):

- Are acceptable alternatives lacking? (description of acceptable alternatives section 2.2)

NO

The use is *non-essential* for society and the substance in this use should be substituted. No further assessment needed.

YES

The use is currently *essential* for society.
Before allowing it, conditions for the use should be set (section IV).

Figure 1: Assessing if a use of a substance is essential for society.

b. Assessing necessity for health or safety and criticality for the functioning of society

The societal needs captured by this criterion are served by the need for a **technical function** that the most harmful substance **provides through a particular use and the context of that use**. Emphasis should be placed on what is necessary for health or safety or critical for the functioning of society, i.e.,

- Only uses of most harmful substances which are needed to ensure a high level of protection of health, security and/or the environment or where the absence of the use would result in unacceptable consequences for the society should be deemed necessary for health or safety or critical for the functioning of society.
- Technical functions of most harmful substances that only impart properties relating to convenience, leisure, decoration or luxury to the user of the final product should normally not be deemed necessary for health or safety or critical for the functioning of society.

Different levels of contextualisation may need to be considered for different uses. Sometimes it is enough to only determine the technical function provided by the substance in the use to conclude that the use is non-essential, but often the context in which the final product is used and provides its service also needs to be considered. For a use to be deemed necessary for health or safety or critical for the functioning of society, the answer to both questions below must be ‘yes’:

- i. Is the technical function of the most harmful substance needed for the final product to deliver its service?
- ii. Does the use of the most harmful substance fulfil at least one element specified in tables 2 or 3 below, so that it fulfils the criterion of being necessary for health **OR** safety **OR** critical for the functioning of society? (i.e. at least one of these three parts of this criterion must be fulfilled).

The fundamental consideration for the question is whether the technical function provided by the substance in the use is at all needed for the final product to deliver its service or for the product’s technical characteristics relevant for its service. If that is not the case, the use is not necessary for health or safety or critical for the functioning of society.

If the technical function is needed for the final product to deliver its service, the next step is to continue the assessment to determine if the use of the most harmful substance is necessary for health or safety, or critical for the functioning of society. This assessment will typically also need to consider a broader context, taking into account the particular setting in which the use or service delivered by the final product takes place (e.g. use in hospitals vs use in people’s houses or use in industrial settings).

In the tables below, elements are specified to prove and verify if a use is necessary for health or safety (table 2) or critical for the functioning of society (table 3). The description for each element aims at giving direction and providing guidance for the assessment to increase predictability and ensure consistency within and across legislation.

Table 2. Non-exhaustive list of elements describing the criterion “necessary for health or safety” and guiding description of uses that could qualify under each element.

Elements	Description
Use of a most harmful substance is necessary for health or safety for one or more of the following elements:	
Addressing sickness and comparable health issues	The technical function of the most harmful substance in the use is necessary for health or safety, such as in order to: • ensure hygiene and cleaning in hospitals and similar settings and situations where a high level of disinfection is required, for example related to surgery (under normal conditions, such as in households, use of a most harmful substance in hygiene and cleaning would not qualify as necessary for health or safety) • prevent transmission of and control diseases (including zoonoses) • provide healthcare and prevent serious illnesses, including mental illnesses. <i>“Illness and similar health conditions”</i> are conditions that negatively impact quality of life and daily function, and/or is burdensome in symptoms and treatments. The necessity of using a most harmful substance to prevent, monitor or treat illness and similar health conditions, should be carefully considered because the use itself could generate adverse effects to human health or the environment.
Sustaining basic conditions for human or animal life and health	The technical function of the most harmful substance in the use is necessary for health or safety, such as in order to: • secure sufficient and safe food and feed, such as uses in the production, processing, storage, distribution and delivery of food for human consumption, uses in the production of plant protection products and biocides and diagnostic tools, used in the context of animal health protection • secure sufficient and clean water • secure clean air • secure heat and shelter for protection from the surrounding environment. The necessity of using a most harmful chemical to secure basic conditions for human or animal life and health should be carefully considered because the use itself could generate adverse effects to human health or the environment.

Managing health crises and emergencies	The technical function of the most harmful substance in the use is necessary for health or safety, such as in order to: • Mitigate the effect of health crises and emergencies • ensure the functioning of emergency services, including ambulance and fire services. The use of the most harmful substance should be directly linked to the crises and emergency operations.
Ensuring personal safety	The technical function of the most harmful substance in the use is necessary for health or safety, such as in order to: • ensure the functioning of personal safety equipment, such as uses in seatbelts, personal protective equipment at the workplace, bulletproof vests, life jackets, helmets, fire alarms • ensure the safety of products, equipment and tools, such as lubrication in vehicle brakes, fire resistance in products anticipated to be heated to a temperature where ignition could occur, or uses for corrosion protection of products used in environments where this is needed.
Ensuring public safety	The technical function of the most harmful substance in the use is necessary for health or safety, such as in order to: • ensure safety of infrastructure, such as road, rail and air safety and building safety (uses in elevators, fire alarms and firefighting equipment) • ensure the functioning of emergency services to prevent danger to the public, such as military, police, anti-terrorism, fire safety services and cyber security • customs control, coastguard. The use of the most harmful substance should be directly linked to the safety operations.

Table 3. Non-exhaustive list of elements describing the criterion “critical for the functioning of society” and guiding description of uses that could qualify under each element.

Elements	Description
Use of a most harmful substance is critical for the functioning of society for one or more of the following elements:	
Providing resources or services that must remain in service for society to function	The technical function of the most harmful substance in the use is critical for the functioning of society, such as in order to: • enable installation, maintenance and transmission of infrastructure and services critical to the society, such as energy conversion, storage and supply (e.g. renewable energy, electricity, oil, gas), mobility and transport (e.g. road-, rail-, air-, waterways, shipping and ports), water treatment and water supply, waste treatment, digital communication and healthcare infrastructure²⁴ • enable the functioning of indispensable digital infrastructures, technologies and services, such as data processing, navigation and sensing • enable the extraction, transformation, recycling and storage of critical raw materials²⁵ or resilience to supply disruption for such materials • enable analysis, measurements, and testing systems for resources and services that are critical for the society; • enable the manufacture, supply, maintenance and recycling of key equipment and components for those resources and services that are critical for society²⁶. <i>“Resources or services that must remain in service for society to function”</i> are those whose failure or degradation would result in significant disruption of public safety and security, or other dramatic consequences. Such resources or services could be public or private and must be contextualised in terms of what the use of a most harmful substance means on a societal (rather than individual) level. The use of the most harmful substance should be directly linked to the services and infrastructures themselves.

²⁴ Directive (EU) 2022/2557 of the European Parliament and of the Council of 14 December 2022 on the resilience of critical entities and repealing Council Directive 2008/114/EC.

²⁵ Proposal from the Commission for a Regulation establishing a framework for ensuring a secure and sustainable supply of critical raw materials, COM(2023) 160 final.

²⁶ See e.g. Regulation (EU) 2023/1781 of the European Parliament and of the Council of 13 September 2023 establishing a framework of measures for strengthening Europe’s semiconductor ecosystem and amending Regulation (EU) 2021/694 (Chips Act).

Providing resources such as infrastructure and equipment to ensure defence and security to society in the face of conventional, non-conventional and hybrid threats	The technical function of the most harmful substance in the use is critical for the functioning of society, such as in order to: • enable installation and maintenance of infrastructure for defence and security • enable manufacture, supply, maintenance and recycling of key equipment and components for defence and security. <i>“Resources such as infrastructures and equipment to ensure defence and security to society in the face of conventional, non-conventional and hybrid threats” are those whose failure or degradation would impede the ability of the European Union or its Member States to protect themselves or their population from such threats.</i> The use of the most harmful substance should be directly linked to the resources such as infrastructure and equipment themselves.
Managing societal risks and impacts from natural crises and disasters	The technical function of the most harmful substance in the use is critical for the functioning of society, such as in order to: • prevent or repair damage to infrastructure from natural disasters such as floods, fires, earthquakes. The use of the most harmful substance should be directly linked to the crisis operations.
Protecting and restoring the natural environment	The technical function of the most harmful substance in the use is critical for the functioning of society, such as in order to: • reduce and mitigate greenhouse gas emissions, such as use for renewable energy technologies and zero-emission transport technologies • reduce water, soil or air pollutants, such as use in scrubber technologies and similar uses • protect ecosystems and biodiversity, such as use for control of invasive species • analyse and monitor pollutants • remediate pollutants in the environment. Society is reliant upon the protection and restoration of the natural environment. The criticality of using a most harmful substance to protect the natural environment, including addressing pollution, should be carefully considered because the use itself could contribute to pollution. Proving criticality should involve

	gathering substantial evidence of the extent to which the use could contribute to compliance with EU legislation and international treaties.
Performing scientific research and development	The technical function of the most harmful substance in the use is critical for the functioning of society, such as in order to: • perform laboratory analysis, measurements and testing carried out under controlled conditions for the purpose of scientific research or development • perform laboratory experiments carried out under controlled conditions in higher education institutions (university level) and research institutes.
Protecting cultural heritage	The technical function of the most harmful substance in the use is critical for the functioning of society, such as in order to: • protect cultural heritage, including in particular monuments, as defined in the Operational Guidelines for the Implementation of the World Heritage Convention²⁷: (a) <i>monuments: architectural works, works of monumental sculpture and painting, elements or structures of an archaeological nature, inscriptions, cave dwellings and combinations of features, which are of Outstanding Universal Value from the point of view of history, art or science;</i> (b) <i>groups of buildings: groups of separate or connected buildings which, because of their architecture, their homogeneity or their place in the landscape, are of Outstanding Universal Value from the point of view of history, art or science;</i> (c) <i>sites: works of man or the combined works of nature and of man, and areas including archaeological sites which are of Outstanding Universal Value from the historical, aesthetic, ethnological or anthropological points of view.</i> “Protecting cultural heritage” should be interpreted as a requirement to focus specifically on conservation of cultural heritage. In certain cases, aspects of decoration or aesthetic value can be recognised as having significant cultural value (e.g. listing as UNESCO World Heritage sites) as well as intangible cultural heritage as defined by UNESCO²⁸ such as traditional craftsmanship

²⁷ UNESCO. Operational guidelines for the implementation of the World Heritage Convention. Retrieved 2023-03-29 at <https://whc.unesco.org/en/guidelines/>

²⁸ Convention for the Safeguarding of the Intangible Cultural Heritage, MISC/2003/CLT/CH/14.

	recognised by UNESCO²⁹. Cultural heritage from all sociodemographic groups should be equally respected and assessed objectively. Use of a most harmful substance for the purpose of protecting cultural heritage must not result in exposure of children or other vulnerable groups. The use of the most harmful substance should be directly linked to the conservation operation, other uses would not qualify as critical for the functioning of society.
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c. Assessing the lack of acceptable alternatives

The fulfilment of this essential use criterion requires that there is a lack of acceptable alternatives, which should be demonstrated via an analysis of alternatives. Accordingly, the assessment of this criterion should at least consist of the two following aspects³⁰:

- i. **identification of possible alternatives** for the use, looking at whether the use of the substance that is being assessed can be replaced by an alternative substance, material, product, process or technology (i.e., what are the possible alternatives that can sufficiently provide the technical function needed for the final product to deliver the expected service). The notion of an “alternative” is usually framed by the particular piece of legislation; **AND**
- ii. assessment of their **acceptability**.

Acceptable alternatives must be capable to provide the function and the level of performance that society can accept as sufficiently delivering the expected service and be safer. As described under section 2.2 of this Communication, the assessment of alternatives is normally defined with specific requirements in each piece of legislation, and for most pieces of legislation, it also includes a technical and/or economic feasibility assessment. As mentioned above, 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 assessment should not be limited to the particular user undertaking the use but relate to the use at market level and regarding societal needs. Consequently, 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. Therefore, the possible alternatives that need to be considered are:

- products in the market in the same product category that do not use the most harmful substance;

²⁹ UNESCO Lists of Intangible Cultural Heritage and the Register of good safeguarding practices. Retrieved 2023-03-29 at <https://ich.unesco.org/en/lists>

³⁰ The way this criterion is defined and proposed to be assessed takes account of the relevant parts of the Montreal Protocol criteria for essential use as well as the Chemicals Strategy for Sustainability.

- the alternatives that have a lower performance, provided it is acceptable from the societal point of view³¹;
- those alternatives that provide a similar technical function and a similar level of performance to those provided by or with the most harmful substance.

Some examples of how alternatives assessment is framed in existing EU legislation are given below.

The *REACH Regulation ((EC) No 1907/2006)*³² sets the framework for registration, evaluation, authorisation and restriction of chemicals. An assessment of alternatives is performed in the context of authorisations and restrictions. Decisions on restrictions based on Article 68(1) need to take into account the availability of alternatives. The assessment is based on information on alternatives including their availability and technical and economical feasibility³³. In the authorisation process, REACH requires an assessment of ‘suitability’ of alternatives to the use of the substance of very high concern, including their technical and economic feasibility. These terms have no definition set in the REACH Regulation. In the area of authorisation, they are framed by the relevant case law³⁴. According to this case law:

- The term ‘suitable’ aims to limit the number of relevant alternatives to the number of ‘safer’ alternatives, meaning substances or technologies whose use entails a lower risk as compared to the risk of using the relevant substance of very high concern.
- In addition, the term ‘suitable’ means that the alternative must be “economically and technically viable”³⁵. Its meaning is not limited to the existence of an alternative *in abstracto*, in laboratory conditions or in exceptional conditions.
- As regards the availability of technical and economic feasible alternatives, the analysis of alternatives must be carried out from the perspective of the production capacities for the alternative substances and the feasibility of alternative technologies, as well as in the light of the legal and factual requirements for putting them into circulation.

The *Regulation ((EU) No 528/2012)*³⁶ sets the framework for the placing on the market and use of biocidal products such as disinfectants, preservatives, rodenticides, insecticides and others, which are intended to control organisms that are harmful to humans, their activities or the products they use or produce (including consumer products), or to animals, or the environment.

³¹ However, the overall service and relevant functions provided by the product of that use should be taken into consideration in the alternative assessment, when considering alternative products, materials, technologies.

³² Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC, OJ L 396, 30.12.2006, p. 1–849.

³³ Annex XV to REACH Regulation.

³⁴ Judgement by the EU General Court of 7 March 2019 in Case T-837/16, paragraphs 71-74.

³⁵ within the meaning of Article 55 of REACH.

³⁶ Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products, OJ L 167, 27.6.2012, p. 1–123.

The Regulation sets exclusion criteria for active substances with certain hazard properties (CMR category 1A and 1B, endocrine disruptors for human health, PBT and vPvB), which are normally not approved. Derogation may be given on the basis of Article 5(2) of the Regulation, which, among other criteria, contains some elements similar to the essential use concept, and more specifically:

- that it is shown by evidence that the active substance is *essential* to prevent or control a serious danger to human health, animal health or the environment;
- the availability of suitable and sufficient alternative substances or technologies shall be a key consideration for approving derogations;
- and the derogated use shall be subject to appropriate risk-mitigation measures to ensure that exposure of humans, animals and the environment is minimised.

The Commission may also allow a Member State to authorise a biocidal product containing a non-approved active substance if that substance is *essential* for the protection of cultural heritage³⁷ and no appropriate alternatives are available (Article 55(3)).

The *Taxonomy Regulation on sustainable investment* ((EU) 2020/852)³⁸ establishes the general framework for determining whether an economic activity qualifies as environmentally sustainable based on its contributions to the six environmental objectives³⁹ set out by the regulation. Criteria for “do no significant harm” (DNSH) to pollution prevention and control⁴⁰ specify as requirements that an activity must not lead to the manufacture, use, or placing on the market of substances meeting the criteria for one of the hazard classes or hazard categories mentioned in Article 57 of REACH, except if it is assessed and documented by the operators that no other suitable alternative substances or technologies are available on the market, and that they are used under controlled conditions.

The *Mercury Regulation* ((EU) 2017/852)⁴¹ allows the manufacturing and placing on the market of new mercury-added products and the use of new manufacturing processes involving the use of mercury or mercury compounds, only if an assessment demonstrates that the new use of mercury would provide significant environmental or health benefits and pose no significant risks either to the environment or to human health, and that no technically practicable mercury-free alternatives providing such benefits are available.

³⁷ So far, only one type of such exemption has been requested, found justified and granted: the protection of cultural goods in museums by use of in-situ generated nitrogen.

³⁸ Regulation (EU) 2020/852 of the European Parliament and of the Council of 18 June 2020 on the establishment of a framework to facilitate sustainable investment, and amending Regulation (EU) 2019/2088, OJ L 198, 22.6.2020, p. 13–43.

³⁹ Climate change mitigation, climate change adaptation, the sustainable use and protection of water and marine resources, the transition to a circular economy, pollution prevention and control, and the protection and restoration of biodiversity and ecosystems.

⁴⁰ Commission Delegated Regulation (EU) 2023/2485 of 27 June 2023 amending Appendix C to the Taxonomy Climate Delegated Act ((EU) 2021/2139).

⁴¹ Regulation (EU) 2017/852 of the European Parliament and of the Council of 17 May 2017 on mercury, and repealing Regulation (EC) No 1102/2008, OJ L 137, 24.5.2017, p. 1–21.

IV. CONDITIONS ASSOCIATED WITH THE DECISION ON AN ESSENTIAL USE

A targeted assessment of the risk to human health and the environment should **establish whether risk management measures and operational conditions** for the use result into emissions and exposure of humans and the environment that are minimised to as low a level as is technically and practically possible. If that is not the case, conditions should be imposed to achieve this objective, as appropriate for each particular piece of legislation.

Principles for setting conditions for uses that are found to be essential for society:

- 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 use⁴² in particular to avoid or minimise exposure of vulnerable groups such as children, pregnant women and elderly people, who are more sensitive to exposure to harmful chemicals.
- ensure incentives for innovation of safe and sustainable alternatives and substitution
 - conditions committing to engage into substitution and to monitor the progress towards substitution (substitution plans), and
 - a time-limit should normally be set for derogations from restrictions and authorised uses.
- ensure availability of information of the use in the supply chain and to consumers and waste operators.

⁴² E.g. Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens, mutagens or reprotoxic substances at work.