Workshop background document

Study supporting the Commission in developing an essential use concept

3 March 2022 (virtual)

This document serves as a background document for the upcoming workshop associated with the study supporting the European Commission in developing an essential use concept. The following sections outline the workshop objectives, the background to the study, and further context on the workshop sessions.

1. Introduction

1.1 Workshop objectives

The aim of the workshop is to consult stakeholders and obtain their views on the essential use concept. Stakeholders will be invited to provide feedback on the preliminary findings of the study in order to inform: 1) further development of the essential use concept; 2) further consideration of how the concept can be operationalised in REACH and in more general terms for other relevant chemicals legislation; and 3) consideration of any potential methodological or knowledge gaps of importance to the concept. An agenda for the workshop can be found in appendix A.

To inform stakeholders and stimulate discussion, the project team will present the overall approach being taken, as well as research carried out so far on insights from legislation that already contain an essential use concept or similar, on legislation that may benefit from such a concept, criteria for the essential use concept and elements to guide its application, and policy options. You can find an overview of study tasks in appendix B.

1.2 Study background

Wood E&IS GmbH ('Wood'), in collaboration with Ramboll and additional scientific advisors[1], has been contracted by the Commission to assist in the development and operationalisation of an 'essential use concept' (ESU) to be applied in EU chemicals legislation.

Legal and political background

The Chemicals Strategy for Sustainability Towards a Toxic-Free Environment[2] proposes the development of a horizontal essential use concept to apply across chemicals legislation. The

[1] Ian Cousins (from Stockholm University), as well as Martin Scheringer and Zhanyun Wang (from ETH Zurich).
[2] https://ec.europa.eu/environment/pdf/chemicals/2020/10/Strategy.pdf

Chemicals Strategy commits 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*"[3].

The development of an essential use concept is aligned with the EU ambition for a toxic-free environment, which is highlighted as a priority in a number of policy strategies including the European Green Deal[4], the Chemicals Strategy for Sustainability, the Zero Pollution Action Plan[5], and the Circular Economy Action Plan[6]. The concept would contribute to reductions in the use, and consequently the emissions, risks and impacts associated with most harmful substances. The concept has the potential to protect the environment and human health from most harmful substances by facilitating the phase out of non-essential uses and therefore preventing potential human and environmental exposure to the most harmful substances.

The overall aim of the essential use concept is to allow systematic decision-making to facilitate the phasing out of the most harmful substances by only allowing them when their use is essential, i.e., necessary for health and/or safety or critical for the functioning of society and if there are no acceptable alternatives from the standpoint of human health and the environment. A similar concept has been used under the Montreal Protocol which saw the phasing out of 98% of ozone-depleting substances between 1989 and 2019 and is considered as the most successful international environmental agreement.

The concept has been investigated for further use in EU chemicals legislation, for example, Cousins et al. (2019) suggested the application of the concept to assess the essentiality of certain uses of PFAS (a large group of very persistent substances which are known to cause harm to the environment and human health).[7]

The ongoing work for the review and the revision of REACH and of some pieces of chemicals legislation presents an opportunity to improve existing chemical regulatory processes. Improving processes to phase out the use of the most harmful substances is imperative given the current challenges in chemical regulation, for example, complex and slow restriction processes and heavy authorisation procedures under REACH. These limitations can delay decisions and actions to adopt appropriate risk management measures for most harmful substances, and therefore can result in exposure of citizens and workers as well as their release to the environment. An essential use concept could help address these limitations by introducing more simplicity, transparency, predictability, and efficiency to prevent uses that are not necessary or critical (in terms of human health and/or the functioning of society) and by providing more regulatory certainty to businesses. It is acknowledged that a horizontal application of the concept could have far-reaching consequences compared to the current system and, therefore, it is key to involve and consult the various actors affected and/or active in the field of chemicals legislation.

The development and application of an essential use concept is intended to encourage innovation in safe and sustainable chemicals to be used as alternatives to the most harmful substances. Last,

[3] https://eur-lex.europa.eu/resource.html?uri=cellar:f815479a-0f01-11eb-bc07-01aa75ed71a1.0003.02/DOC_1&format=PDF
[4] https://ec.europa.eu/info/sites/default/files/european-green-deal-communication_en.pdf
[5] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52021DC0400&qid=1623311742827
[6] https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1583933814386&uri=COM:2020:98:FIN
[7] https://pubs.rsc.org/en/content/articlelanding/2019/em/c9em00163h

setting clear and robust criteria would allow justification decision making on discontinuing or continuing uses of these substances.

Other than the Montreal Protocol, which covers a very defined set of circumstances, there has been little practical application of the essential use concept in chemicals policy to date. It is therefore important to understand how the above potential benefits would be realised in practice.

Aims and objectives of the study

The overall objective of this project is to assist the Commission in the development and operation of an 'Essential Use Concept' (ESU) to be applied horizontally in EU chemicals policy. The work carried out under this contract is intended to feed into the following areas of ongoing work:

- Commission document on the horizontal criteria and application of the concept of Essential Uses across chemicals legislation;
- The targeted revision of REACH; and
- Revision processes of other pieces of chemicals legislation (such as the Cosmetic Products Regulation, the Toys Safety Directive, etc.), as relevant.

The project tasks are being supported by broader stakeholder consultation. This includes contribution to questions on the essential use concept to the public consultation on the targeted revision of REACH (currently active until 15 April 2022), input gathered from a range of stakeholders through this workshop, as well as a targeted survey and interviews for stakeholders in affected sectors, stakeholders with expertise and interest in the topic, and relevant Member State institutions (to be conducted).

2. Information on plenary sessions

2.1 Session on fundamentals and definitions of the essential use concept

The first session of the workshop will involve a presentation on the 'fundamentals' and definitions of the essential use concept. This will be an important session to ensure a common understanding of the ESU concept and to avoid any misunderstandings or misinterpretations of the concept.

Some key points will be further elaborated and discussed in the workshop, as listed below:

- The ESU concept would be applied only to the most harmful substances[8].
- The underlying logic of the concept is to more effectively phase out the most harmful substances and only allow uses that are essential. The essential use concept embeds two main criteria:

[8] Most harmful substances are defined in the Chemicals Strategy for Sustainability as chemicals that cause cancers, gene mutations, affect the reproductive or the endocrine system, or are persistent and bioaccumulative; chemicals affecting the immune, neurological or respiratory systems and chemicals toxic to a specific organ.

- The use of a substance is **necessary** for health, safety **or** is **critical** for the functioning of society, **and**
- There are no alternatives that are acceptable from the standpoint of environment and health.

- Essentiality (based on criteria covering the **necessity** for health and safety, the **criticality** for the functioning of society, and the assessment of **alternatives**) of the use of a substance would be assessed, not the essentiality of the article / product which it is used in. This relates to the technical function[9] provided by the substance in the specified use.
- The concept would mean that decisions on derogations to restrictions and/or authorisations for the most harmful substances would be based on essentiality of the particular use

2.2 Session on lessons learnt from legislation with similar concepts

An analysis of EU (and wider) legislation that already contain elements of an essential use concept (or similar) has been carried out. The purpose was to analyse if and how current legislation applied concepts of essential use (or the individual components of the concept – see section 2.3) that could provide important 'lessons learned' to inform the concept further. An overview of exemplary legislation and the components of essential use concept currently applied is shown in the table below:

Table 2.1 Overview of essential use concept (components) in EU legislation

Legislation	Necessary for health/safety	Critical for the functioning of society	Assessment of alternatives
Montreal Protocol	✓	✓	✓
Biocidal Products Regulation	✓	✓	✓
Plant Protection Products Regulation	✓	-	✓
RoHS Directive	✓	✓	✓
REACH (authorisation)	-	-	✓
Cosmetic Products Regulation	-	-	✓
Safety of Toys Directive	-	-	✓
Taxonomy for sustainable activities	✓	✓	✓
Food Contact Materials Regulation	-	-	-
POPs Regulation	-	-	✓

[9] The technical function describes the role that the substance fulfils when it is used (what it actually does as such in a process or what it actually does in a mixture or article)

From the analyses completed, a number of insights can be drawn from these existing pieces of legislation. These are briefly discussed in the table below. This can form the basis for wider discussion during the workshop.

Table 2.2 Overview of essential use concept (components) in existing legislation

Aspect	Key insights
Existing application of essential use	In addition to the Montreal Protocol, a small number of examples - The Biocidal Products Regulation is the one specific case where this is considered. Even here, it is noted that a specific definition or criteria have been set out in the consideration of essential uses.
Limited use of the concept 'in practice'	There are very few examples where derogations are granted based on essential use criteria
Legislation under revision or newly published	Some pieces of legislation are undergoing revision (e.g. on toys, cosmetics, RoHS, FCM) while others e.g. taxonomy have been published containing reference to 'essential use' but have not fully defined how this is to be implemented.
Ambiguity / Differences in definitions	In many cases reference to the 'essential' criteria is implicit or refers only to one aspect (e.g. assessment of alternatives – suitable vs feasible (economic/technical)). Overall, there is a range of definitions/interpretations as to what 'essential' (or similar concept) means.
What is the focus point of the essential use concept (or similar concept to essential use)?	It is highlighted that essentiality (or similar concepts in existing legislation) may be very different for different uses. No two cases in which the essential use concept could be applied are the same. This applies both when comparing the process under two different pieces of legislation and case within the same legislation. For example, the situation would be very different between biocidal products being used in public hygiene compared to their use to protect infrastructure.
Efficiency vs effectiveness	It is noted that proving the case for an exemption (and implicitly 'essentiality' to a degree) in practice can be an onerous exercise (the process of collating data for assessing derogations is a time-intensive process) without a certainty of the outcome. Clearly set criteria for exemptions can therefore provide a better certainty as well as speed up decision making.

2.3 Session on criteria for the essential use concept

This session will provide further information on the initial criteria for the ESU, as established in the Chemicals Strategy for Sustainability and drawn from the Montreal Protocol. As a reminder, these first two criteria are:

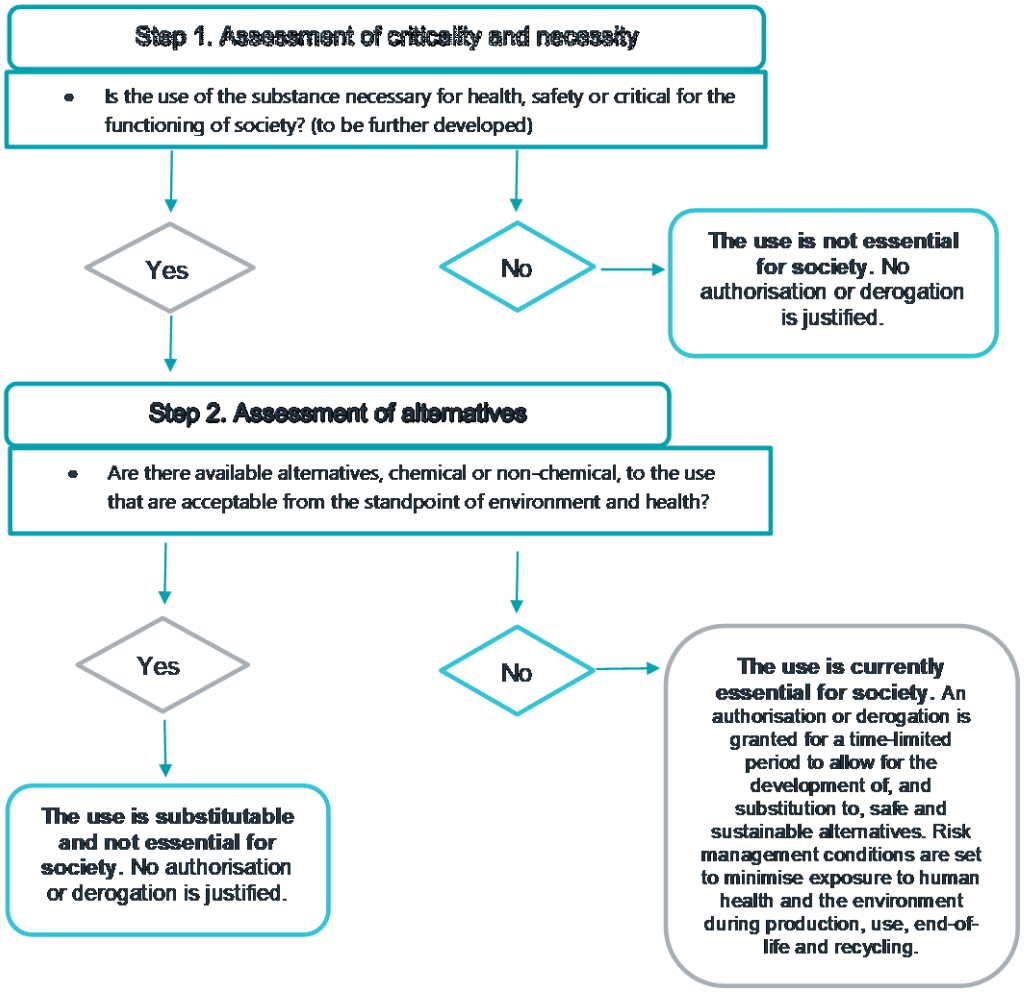
"… ensure that the most harmful chemicals are only allowed if

- *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."*

To exemplify interpretation of the criteria thus far, uses of the most harmful substances that would qualify as "necessary for health, safety or critical for the functioning of society" would primarily be

uses that are important for basic conditions for human life, health and infrastructure: for example uses that provide clean and sufficient food and water, energy, advanced healthcare and security. Integration of cultural aspects in the concept will also be explored. Uses of the most harmful chemicals that would potentially not qualify as critical or necessary for health and safety would be e.g. related to luxury, decoration, leisure or convenience.

The criteria are demonstrated in the following decision-tree:



In this workshop we will present work done so far to refine the criteria, including consideration of scientific and technical aspects, socio-economic aspects, legal aspects, timing, clarity, applicability to risk management, accordance with the Chemicals Strategy for Sustainability, measurement and monitoring, flexibility, applicability across legislation, relevance to the wider chemical universe, and objectivity.

2.4 Session on legislation that may benefit from the essential use concept

This session will involve a presentation of the work conducted by the project team to identify EU legislation (other than REACH) that may benefit from the introduction of an essential use concept.

A selection of (up to) eight pieces of legislation in addition to REACH will then be considered further in this project. In this workshop, we will focus on the following 5 pieces of legislation for discussion:

- REACH
- Toys Safety Directive
- Cosmetic Product Regulation
- Food Contact Materials Regulation
- RoHS Directive

An overview of preliminary findings from the research so far, highlighting specific aspects of how the essential use concept could potentially provide benefits to the different pieces of legislation is provided below:

Table 2.3 Overview of essential use concept (components) in existing legislation

Legislation	How could an ESU concept benefit this legislation?
REACH Regulation (1907/2006/EC)	Allow easy/early indication to manufacturers /users if authorisation is likely to be successful and provide saving of time and effort. Provide simplified, systematic criteria for assessing derogations from restrictions and authorisation proposals.
Biocidal Products (Regulation (EU) No 528/2012)	The BPR is one piece of existing legislation where aspects of 'essentiality' are already considered. However, it is noted that there is not a specific 'definition' or criteria defined for determining if use is essential.
Cosmetic Products Regulation (1223/2009/EC)	Cosmetic Products Regulation is currently undergoing revision. The ESU would need to ensure that risk management under this legislation is efficient and does not undermine the primary objective of ensuring safe cosmetic products and is consistent and coherent with other related legislation (e.g. REACH, Toys). Could allow a systematic (and relatively rapid) identification of exemptions in cases where use of the most harmful substances provides a suitable benefit in terms of criticality for society. An essential use concept can provide a clear and consistent definition and procedure for determining if there are no 'suitable' alternatives.
Food Contact Materials (Regulation (EC) 1935/2004)	FCM legislation is currently undergoing revision. Could the revision i) include a generic approach to risk management of substances with certain hazardous properties; ii) consequently require a similar approach to applying possible derogations for those substances e.g. as currently used in other consumer products legislation (e.g. cosmetics, toys)? The ESU can therefore help guide the revision of the FCM legislation in terms of applying effective and proportionate risk management.
Safety of Toys Directive (Directive 2009/48/EC)	The Directive is undergoing review, so the development of the ESU could help inform the revision and ultimately strengthen the overall objective of the legislation – to ensure products put on the market are safe. For example, the scope of existing restrictions could be expanded to cover more hazard classes of the most harmful substances (though noting that the latter is envisaged regardless of ESU). The ESU could ensure that restriction/derogation process is carried in way that is consistent and coherent with other related legislation (e.g. REACH, Cosmetics).

Legislation	How could an ESU concept benefit this legislation?
Restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS) (Directive 2011/65/EU)	The exemption criteria are reviewed in the currently ongoing review of the RoHS Directive. This offers the potential to improve the efficiency of the process for updating the lists of substances in Annexes II, II and IV carried out under Art 6, using a defined criteria for essential use, applied to specific uses of the substance. Also offers the potential for closer alignment and better coherence with other EU legislation dealing with electronic waste (e.g. the End of Life Vehicles legislation), for example by applying the same derogation criteria. It is noted that the Directive must ensure that changes made to Annexes II, II and IV "does not weaken the environmental and health protection afforded by Regulation (EC) No 1907/2006 (REACH)". The ESU could therefore also ensure easier alignment between RoHS and REACH.
Plant Protection Products (PPP) (Regulation (EC) No 1107/2009)	The ESU concept could [depending on final criteria and implementation] help apply relatively quick and consistent decision making when considering authorisations under Art 4(7). It could also have the added benefit of improved efficiency for the legislation by deterring operators from submitting applications for derogation in the first place. Noted that for the emergency procedure (Art 53) there is a need to make decisions very quickly (but with a degree of flexibility built in), but their evaluation by the Commission could profit from uniform criteria. ESU concept could allow quicker and more systematic comparison of alternatives when assessing candidates for substitution and could aid in approval of derogations.

2.5 Session on policy options for REACH

Context

According to the Chemicals Strategy for Sustainability, the concept of essential uses should be applied in all relevant EU legislation for both generic and specific risk assessments. The integration of the concept in REACH is one of the key components of the ongoing reform of the restriction and authorisation processes in REACH. In particular, the criteria for essential use should be used for making decisions on authorisations and on whether or not derogations to restrictions would be justified for a particular use. Those criteria would replace the current comparison of costs and benefits and the assessment of alternatives[10], by an assessment of essentiality based on criticality for the functioning of society, necessity for health and safety and an assessment of alternatives that are acceptable from the standpoint of environment and health. The remaining process for the final Commission decision on derogations and authorisations would, in principle, be no different from the current situation (see below).

The aim of this exercise is to simplify and speed up decision making in the authorisation and restriction processes and provide more clarity and legal certainty on these processes overall. In particular, it would streamline procedures where the main decision parameters are clear, and free the (authorities) resources for other risk management tasks and actions.

[10] Cost and benefits comparison and alternatives assessment are currently applied in authorisations (when applying Article 60(4)) and also in considering derogations from restrictions for particular uses (when restrictions are based on Articles 68(1) and 69(2)).

Main elements for discussion in the workshop (see also flowchart in the annex)

The criteria to prove that a use is essential will be defined horizontally for application across legislation (these criteria will be discussed in the morning session). The most important element requiring discussion specifically for REACH is therefore the way in which concretely the criteria and their individual elements should be applied, including possible options for simplification. One of the possibilities for simplification can be to consider screening steps as regards available alternatives and criticality of the use for the functioning of society or its necessity for health and safety. The screening step, if useful and feasible, would precede, and in some cases allow to avoid, an in-depth assessment.

The degree of information needed to take decisions on whether or not a use is essential may differ from case to case depending in which step the decision is taken. In some cases, initial information about the use may be sufficient to take decisions already at a screening step. Stakeholders are invited to discuss the feasibility of a stepwise approach for information to be submitted for the assessment of essentiality.

The screening steps would address criticality for the functioning of society/necessity for health and safety and the availability of alternatives. The screening steps could be done i) in parallel for both elements of the criteria, ii) first for criticality/necessity, or iii) first for availability of alternatives. If the result is clearly yes on criticality/necessity, a subsequent assessment of alternatives would be needed. It would however require further discussion to see whether there are cases for which it is possible to simplify such assessment or if a subsequent detailed scientific/technical assessment of alternatives would be needed. If the result is clearly no on criticality/necessity *or* yes on alternatives, no further scientific/technical assessment would be needed and a decision that the use is not essential and that a derogation or authorisation is not justified could already be taken after the initial screening.

Main elements for discussion in the workshop for a stepwise approach for assessing essential use under REACH

Step one:

- Initial screening of **alternatives**, identifying if:
    1. there is a clearly identifiable alternative in the same product category, or
    2. not so clear-cut (remaining cases); to be discussed whether at this stage it would be possible to identify whether there is clearly no alternative
- Initial screening of **criticality/necessity**, identifying those cases where a use is:
    1. clearly critical/clearly necessary, or
    2. clearly non-critical/unnecessary, or
    3. not so clear-cut (remaining cases)

*Where no further scientific/technical assessment is needed, decisions on the derogation or authorisation could already be taken at this stage **(Step 3)**.*

Step two: where needed, further scientific/technical assessment (if appropriate after adjustment of information requirements at the screening stage)

Step three: decision on the derogation or authorisation.

2.6 Approach to impact assessment and gaps identified so far

This session will involve a presentation of the aims, objectives, and workplan for the assessment of impacts of options. The main objective of this task is to provide information to support an Impact Assessment of the policy options prioritised in the project. This will assess if future legislative or non-legislative EU action is justified and how such action can best be designed to achieve desired policy objectives. It will focus specifically on REACH, with only a broader consideration for other legislation.

The task will identify environmental, economic, and social impacts of the policy options for introducing an essential use concept in REACH. The nature of each impact, in terms of affected stakeholders, magnitude, temporality, permanence, frequency and certainty etc. will be described, and then a qualitative analysis and a quantitative / semi-quantitative cost-benefit analysis will be conducted.

The workshop will provide further detail on the methodology as well as types of impacts anticipated. This will also provide an opportunity for stakeholders to highlight any anticipated impacts of concern.

3. Discussion points for break-out sessions

The breakout sessions will be the primary forum of input and discussion from participants during the workshop. For fruitful discussion, it is important that the sessions focus on a limited number of defined specific discussion points.

3.1 Morning session – Criteria for the essential use concept

To objective of the morning session will be to engage in a discussion to feed into the current work on the **refinement of criteria for the essential use concept**, as well as guidance on its implementation and application in chemical legislation (Task 3). This is split into two specific sessions:

- **Morning session 1)** Criteria to define if use is necessary for health, safety or critical for the functioning of society.
- **Morning session 2)** Criteria to define whether there are alternatives that are acceptable from the standpoint of environment and health.

The specific discussion questions to be considered in these sessions are detailed in the table below.

Table 3.1 Discussion points for morning session

Theme	Discussion question(s)
Assessment of necessity for health and safety and of criticality for the functioning of society	• What are key elements required to assess if the use of a substance is necessary for health and safety? • What are key elements required to assess if the use of a substance is critical for the functioning of society? • What are key elements to be considered to include cultural and heritage aspects in the decision on whether the use of a substance is critical for the functioning of society?
Assessment of alternatives	• What are key elements required for the assessment of acceptability of alternatives from the standpoint of the environment and health? • What would be key steps in the assessment of alternatives? • Which actor(s) should provide information/evidence on alternatives? In what format? • What are key lessons learnt from analysis of alternatives under REACH and other legislation that could be considered for this step in the essential use concept?
Application of the essential use concept	• Is the terminology used in the concept (e.g. essentiality, necessity, criticality, etc.) sufficiently clear? What areas of the concept remain unclear in terms of definitions? How could these be improved? • Is the step-by-step (described in the earlier section) assessment sufficiently clear? Which steps or sub-steps remain unclear? How could this be improved? • What evidence is needed at each step in the presented assessment above (e.g. data sources/verification process) to prove a use is essential? Who should provide this information? • What degree of flexibility is required for the application of the criteria? An example would be provisions for emergency uses (e.g. medical circumstances). Can you think of other similar examples where flexibility in the application of the criteria or process would be justified

3.2 Afternoon session – Policy options

The objective of the afternoon session will be engaged in a discussion to feed into the current work to **refine a series of policy options to operationalise the concept in chemicals legislation**, presenting alternative options to achieve the objectives set out in the Chemicals Strategy for Sustainability (Task 3). This will focus on definition, scoping and feasibility (considering elements of effectiveness, efficiency and coherence) of the options (as discussed in Section 2.5).

This is split into two specific sessions:

- **Afternoon session 1)** Policy options for REACH.
- **Afternoon session 2)** Policy options for other legislation

Policy options for REACH

The specific discussion questions to be considered in these sessions are detailed in the table below.

Table 3.2 Discussion points for afternoon session 1

Theme	Discussion question(s)
Feasibility/usefulness of screening steps	• Do you think that initial screening steps could in principle simplify and speed up decision-making? a) If yes, do you think the two screenings (on criticality/necessity and on alternatives) should be done simultaneously or should they be done one after the other? If the latter, which one should be done first and why? b) What would be the main benefits of the screening steps? c) What would be the main challenges of the screening steps? d) What would be the information required and expertise needed for the screening on criticality/necessity and on alternatives? e) Would it be possible to determine already in the screening that there are no available alternatives?
Information requirements for proving that a use is essential	• What are, in your view, the information requirements needed to make a full assessment of criticality/necessity and alternatives and subsequently take a decision on essentiality of a use? What would be the advantages and disadvantages of these information requirements? • Do you think it is feasible to simplify the assessment of alternatives for clearly critical uses (even if no clear alternative has been identified in the screening)? If so, why and under which circumstances? What would be the advantages and disadvantages? • Do you think that information requirements should be the same in all cases or should there be a possibility to adapt them at the screening stage to allow for simplification and better targeting, in particular for clearly critical uses? What would be the advantages and disadvantages of either approach?
Feasibility/usefulness of a fall-back mechanism for emergency situations	• Do you see a need for an additional fall-back mechanism in decision-making on essential uses for emergency situations (given the possibilities already offered by Articles 2(3) and Article 129 of REACH)? If yes, why and how could it be done?

Policy options for other legislation

The specific discussion questions to be considered in both of the afternoon sessions are detailed in the table below.

Table 3.3 Discussion points for afternoon session 2

Theme	Discussion question(s)

Benefits from ESU in legislation other than REACH	• Do you think the legislation [Cosmetic Products Regulation, RoHS Directive, Safety of Toys Directive or Food Contact Materials Regulation] would benefit from an essential use concept?
	  ○ If so, what would be the advantages?
	  ○ If not, why not?

Feasibility	• How do you think the essential use concept should be implemented for this legislation [Cosmetic Products Regulation, RoHS Directive, Safety of Toys Directive or Food Contact Materials Regulation]? • Could the horizontal criteria for essential use (discussed in the morning) be directly implemented in this legislation [Cosmetic Products Regulation, RoHS Directive, Safety of Toys Directive or Food Contact Materials Regulation]? Do you see the need for differentiation in these criteria, based on the piece of legislation? • What would be the key practical challenges in implementing the ESU concept in this legislation [Cosmetic Products Regulation, RoHS Directive, Safety of Toys Directive or Food Contact Materials Regulation], in particular considering the existing provisions of the legislation as well as the types and characteristics of products regulated in this legislation? • Would the ESU criteria (discussed in the morning) be aligned with the objectives and specificities of the legislation [Cosmetic Products Regulation, RoHS Directive, Safety of Toys Directive or Food Contact Materials Regulation]? For example, 1) whether and how conditions for minimising exposure or emissions from an essential use are appropriate to ensure cosmetic products safe for human health under Cosmetic Products Regulation or safe toys under the Toys Safety Directive, 2) when safety for human health is assessed in addition to the essential use criteria, at which stage, in relation to the essential use assessment, should it take place?
Flexibility in criteria and feasibility/usefulness of a fall-back mechanism for emergency situations	• What degree of flexibility is required for the application of the criteria in this legislation [Cosmetic Products Regulation, RoHS Directive, Safety of Toys Directive or Food Contact Materials Regulation]? An example would be provisions for emergency uses (e.g. medical circumstances). Can you think of other similar examples where flexibility in the application of the criteria or process would be justified in this legislation?
Coherence with other EU legislation	• Could ESU criteria improve the coherence of the legislation [Cosmetic Products Regulation, RoHS Directive, Safety of Toys Directive or Food Contact Materials Regulation] with other EU legislation? If so, which? Do you have examples?

4. Logistics of the workshop

All stakeholders are invited to observe the presentations in the plenary sessions and to ask questions via the Q&A / chat function. However, to accommodate a manageable number of

participants for interactive discussion and to ensure a balanced representation of views, a smaller number of stakeholders have been invited to participate in breakout groups.

The agenda for the workshop, including timings for plenary sessions and breakout sessions, is provided in the Appendix of this document.

The workshop will be hosted using Microsoft Teams. There will be two links: one for the plenary sessions and one for the break-out groups (if you have been invited to participate to the break-out groups).

A dedicated email address (essential.use.concept@woodplc.com) has been created by Wood to manage any questions from participants.

4.1 Breakout groups

Participants invited to the breakout groups are invited to pre-register interest (via the Microsoft form provided in the invitation email) in their preferred discussion topic for the afternoon session on policy options for legislation other than REACH. The project team will aim to allocate participants one of their top two choices of legislation.

We will aim to include a range of stakeholder types in each group to ensure a balanced range of views are captured. Participants invited to breakout groups will automatically be moved into a pre-assigned breakout group when the session begins.

In the morning, each breakout group will discuss the same topic in parallel, i.e. criteria to define if use is necessary for health, safety or critical for the functioning of society and criteria to demonstrate that there are no alternatives that are acceptable from the standpoint of environment and health.

In the afternoon, each breakout group will first discuss policy options for REACH and then, in the next session, one other piece of legislation (either further discussion on REACH, or food contact materials, Cosmetics, Toys, or RoHS).

Two plenary sessions are scheduled for the rapporteur from each group to provide a short summary of key talking points expressed by the different stakeholder groups.

Appendix A Workshop agenda

Schedule	Session
09:30 – 09:40	Plenary session • Welcome and speech by Patrick Child, Deputy Director-General DG ENV, European Commission • Presentation of structure of workshop and desired outcomes by Wood project team.
09:40 – 10:10	Plenary session (Wood project team) • Fundamentals / definitions • Overview of methodology and consultation, • Q&A
10:10 – 10:45	Plenary session (Wood project team) • Lessons learnt from the essential use concept in the Montreal Protocol and from legislation with similar concepts (Task 2 partly),. • Criteria for ESU (Task 3 partly) • Q&A
10:45-11:30	Break-out groups • Criteria to define if use is necessary for health, safety or critical for the functioning of society
11:30 – 11:45	**Break/coffee**
11:45 – 12:30	Break-out groups • Criteria to define whether there are alternatives that are acceptable from the standpoint of environment and health
12:30 – 13:30	**Break/Lunch**
13:30 – 14:00	Plenary • Feedback from break-out groups (Wood project team)
14:00 – 14:45	Plenary Introduction by Kristin Schreiber, Director DG GROW, European Commission: operationalising the concept of essential uses in specific legislation (REACH, cosmetics, toys) Presentation of preliminary findings (Wood): • Legislation that could benefit from an essential use concept (Task 2 partly) • Policy options for ESU in chemicals legislation (REACH and other legislation) (Task 3 partly) • Approach to impact assessment • Q&A
14:45 – 15:45	Break-out group (specific participants and discussion points tbc) • Policy options for REACH
15:45 – 16:30	Break out groups (specific participants, legislation and discussion points tbc) • Policy options for other legislation (+1 group continuing on REACH) • Other legislation tbc – could include, cosmetics, toys, FCM, RoHS
16:30 – 16:45	**Break/coffee**
16:45– 17:15	Plenary • Feedback from break-out groups (Wood project team)
17:15-17:30	• Close by Cristina de Avila, Head of Unit, DG ENV, European Commission

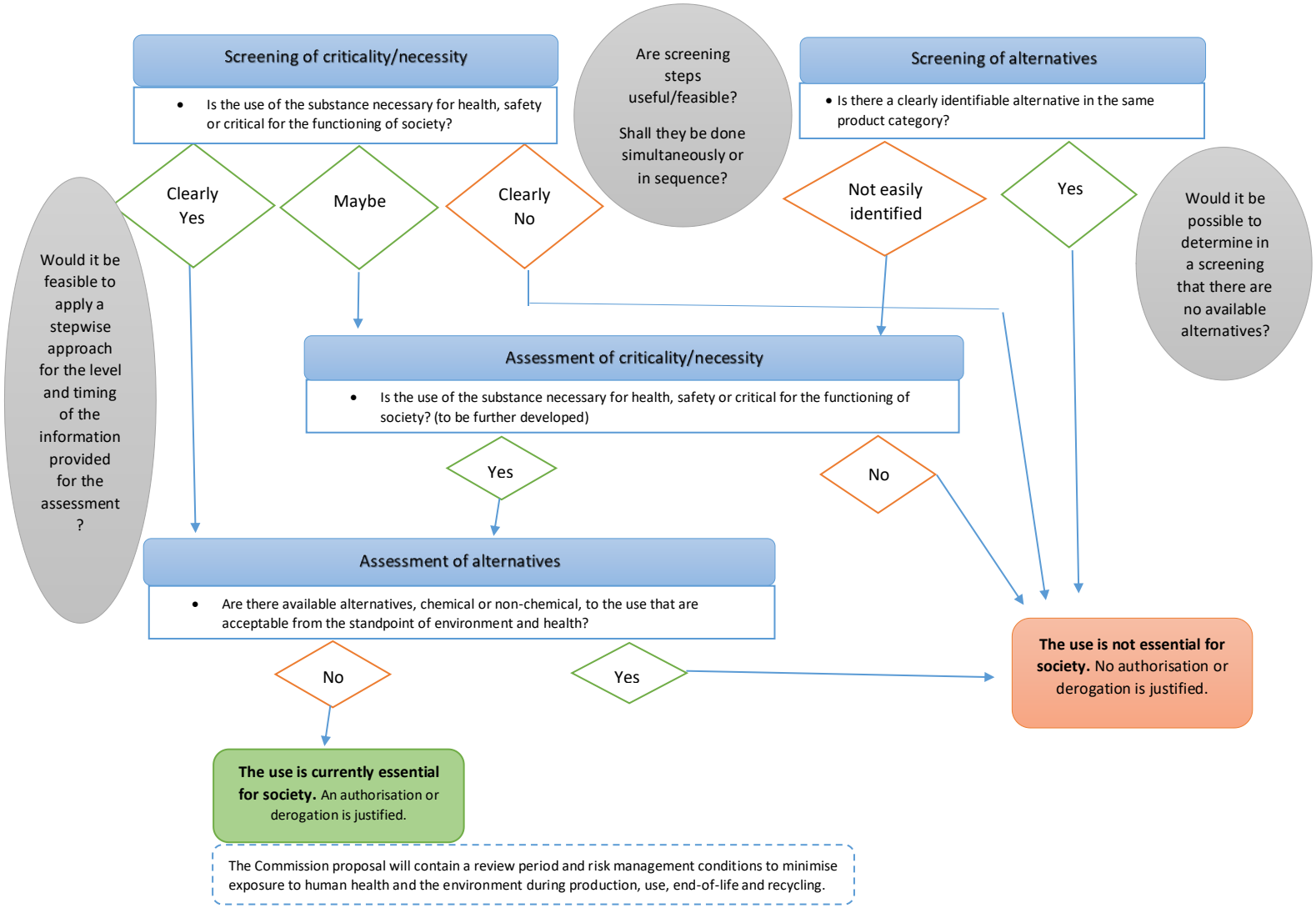
Appendix B Overview of study tasks

The tasks conducted as part of this project include:

- Task 1: Screening of legislation and stakeholder mapping;
  - Screening to identify relevant existing EU chemicals legislation that already contain or will benefit from an essential use concept.
  - Screening and mapping key stakeholders for involvement in consultation.
- Task 2: Gathering and analysis of information;
  - Analysis of legislation to identify lessons learnt from legislation which already includes an essential use concept or similar.
  - Analysis of definitions and additional information.
- Task 3: Identifying elements and testing the application of the concept of essential uses;
  - Developing and refining the most appropriate definitions and criteria for an essential use concept, and the main elements needed to apply this to chemicals legislation.
  - Analysing and refining the policy options for application and operation of an essential use concept in practice.
  - Developing case studies to assess how the essential use concept developed would have operated in practice in the case of previous cases of restrictions or authorisations of chemicals.
- Task 4: Assess the impact (costs and benefits) of the consequences of introducing the concept in REACH;
- Task 5: Holding a stakeholder workshop.

Appendix C Options for assessment of essential uses in REACH

Flowchart - Options for assessment of essential uses in REACH



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Document revisions

No.	Details	Date
1	Draft Background document workshop	7/2/2022
2	Revised background document workshop	16/2/2022
3	Revised background document workshop	20/2/2022