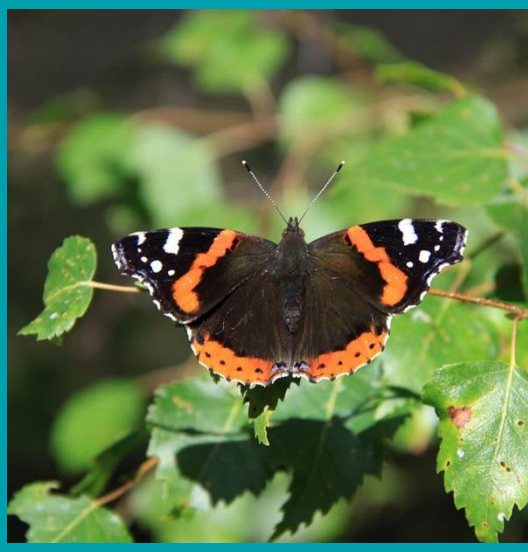
European Commission

Supporting the Commission in developing an essential use concept

Workshop report



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Report for

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Document revisions

No.	Details	Date
1	Draft workshop report	22 March 2022
2	Final workshop report	26 April 2022

Contents

Abbreviations

Abbreviation	Meaning
BPR	Biocidal Products Regulation
CBI	Confidential business information
CMR	Carcinogenic, mutagenic or reprotoxic
CPR	Cosmetic Products Regulation
ECHA	European Chemicals Agency
ED	Endocrine disruptors
EEA	European Environment Agency
EFSA	European Food Safety Authority
ELV	End-of-life vehicles
FAQ	Frequently Asked Questions
FCM	Food contact materials
GRA	Generic approach to risk management
MSCAs	Member States Competent Authorities
NGO	Non-Governmental Organisation
PBT / vPvB	Persistent, bioaccumulative and toxic / Very persistent and very bioaccumulative
PFAS	Perfluoroalkyl and Polyfluoroalkyl Substances
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
POPs	Persistent organic pollutants
Q&A	Questions and Answers

1. Introduction

1.1 This workshop

Wood E&IS GmbH ('Wood'), in collaboration with Ramboll and additional scientific advisors, has been contracted by the European Commission to conduct a *'study supporting the Commission in developing an essential use concept'*. The full terms of reference for this study are available on the Commission webpages[1].

On 3rd March 2022, a stakeholder workshop was held as part of this project. The workshop was held remotely via videoconference and was attended by over 650 participants. Stakeholders participating in the workshop covered a broad range of different stakeholder types (including industry, NGOs, academia, national authorities, agencies, international organisations).

1.2 This report

This report provides a summary of the main discussion points from the workshop. The report is presented according to the running order of the workshop, including:

- Introduction, including policy background, objectives and format (Section 1).
- The main content of the workshop including summary of key discussion points from the plenary and break-out group sessions:
  - Morning session (Section 2).
  - Afternoon session (Section 3).
- Details of next step (Section 4).
- Annexes of additional information:
  - The agenda for the workshop - Appendix A.
  - Presentation slides presented at the workshop - Appendix B.

It is important to note that the discussion points summarised in this report do not represent formal conclusions of the study. We appreciate there are a range of opinions on the issue of essential use, and the workshop aimed to capture the various points made. The ultimate goal is for this workshop to inform how the essential use criteria and policy options can most effectively be developed and implemented.

[1] https://circabc.europa.eu/ui/group/a0b483a2-4c05-4058-addf-2a4de71b9a98/library/1ca724c4-d0a9-4ae1-8f3e-10b1aab4fc90/details

1.3 Policy background and context

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 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 proven essential for society, 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 other 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[8] as well as their release to the environment.

[2] https://ec.europa.eu/environment/pdf/chemicals/2020/10/Strategy.pdf
[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
[8] Note that the protection of workers is also covered by a number of pieces of EU legislation other than REACH including the occupational safety and health (OSH) Framework Directive (Directive 89/391 EEC) and the Chemicals OSH legislations (Carcinogens, Mutagens and Reprotoxicants Directive 2004/37/EC, Chemical Agents Directive 98/24/EC and Asbestos at Work Directive 2009/148/EC.

An essential use concept could help address these limitations by introducing more simplicity, transparency, predictability, and efficiency in the assessment of derogations to restrictions and authorisations, to prevent uses that are not proven essential for 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, setting clear and robust criteria would allow justification to be made in the 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 and also what the costs will be.

1.4 Objectives of the workshop

The key aims of the workshop were to:

1) Invite stakeholders to provide feedback on the research completed so far of the study in order to inform:
    - Further development of the essential use concept.
    - Further consideration of how the concept can be operationalised in REACH and in more general terms for other relevant chemicals legislation.
    - Consideration of any potential methodological or knowledge gaps of importance to the concept.
2) To inform stakeholders and stimulate discussion, the project team presented 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.

It should be noted that the focus of the workshop was on evidence gathering rather than seeking validation of results. The study being carried out is ongoing and while a number of the preliminary tasks (see Section 2.2) have been completed, the main work on the data gathering and analysis to refine the essential use criteria and policy options, as well as the impact assessment of its implementation are still in the early stages. The discussions at the workshop and the comments and feedback received from stakeholders are an important component of this work.

1.5 Workshop format

The workshop consisted of plenary sessions and break-out groups:

1) **Plenary sessions**

- **Aim:** for the project team to present key information about the study (including project background, context, approach, the definitions, fundamentals, criteria and policy options) and to provide feedback from the break-out groups (see below).
- **Access:** open to all participants.
- **Format:** The plenary sessions included introductory remarks by the Commission and presentation by the project team. The large number of participants meant that a detailed 'Q&A' plenary session was not feasible, however participants were able to submit comments or questions in the 'chat'.

2) **Break-out groups**

- **Aim:** the primary forum of input and discussion from participants at the workshop.
- **Access:** Open to a sub-group of participants only[9].
- **Format:** In total there were 6 groups of ~20 participants (~125 participants in total). Each group was assigned a facilitator and rapporteur from the project team. Each session focussed on specific aspects of the essential use concept criteria and policy options and were framed within specific discussion points.
  - Morning sessions - refinement of criteria for the essential use concept:
    - Criteria to define if use is necessary for health, safety or critical for the functioning of society.
    - Criteria to define whether there are alternatives that are acceptable from the standpoint of environment and health.
  - Afternoon sessions - refinement of policy options to operationalise the concept in chemicals legislation.
    - Policy options for REACH.
    - Policy options for other legislation.

1.6 Stakeholder comments and questions

Throughout the workshop, inputs from stakeholders, across both the plenary and break-out group sessions have provided a huge amount of valuable information and insight that is beneficial to this study.

Due to the large number of participants (650+) it was not possible to respond fully to all comments or questions posted in the 'chat' box during the workshop itself. Over the course of the workshop, over 1,000 comments or questions were made in the Teams chat. While dedicated Q&A sessions were included at various points throughout the workshop, it was not possible to cover all points made in the chat.

[9] A full discussion of the selection criteria for the break-out groups is provided in Section 1.4.

The project team have reviewed all the questions and comments posted following the workshop. As mentioned above, the purpose of the workshop was for evidence gathering rather than presentation of final results for validation, therefore for many of the questions or comments that were made, it is not possible to provide definitive answers, and the points made will be used to feed into the project tasks developing the criteria and policy options for the concept.

It is noted that most comments provided in the chat were providing insights or questions that feed into the main discussion points covered throughout the workshop (e.g. relating to the essential use criteria or policy options). Key recurring comments or questions on these aspects are summarised in the sections below.

As indicated during the workshop conclusions, in cases where workshop participants raised specific questions requiring a direct response or clarification (e.g. on definitions, fundamental aspects and the scope of the study), a separate FAQ will be provided by the Commission at a later stage following this report.

1.7 Workshop participants

1.7.1 Overview of workshop participants

A total of 675 participants registered interest in the workshop and took part in the plenary session. The table below shows the stakeholder balance between registrants.

Stakeholder type	Number registered	(as percentage / %)
Trade association	201	30%
Company – chemical manufacturer / supplier	109	16%
Company – downstream user of chemicals	107	16%
Company – other	16	2%
Company – both manufacturer and downstream user of chemicals	4	1%
Member State institution / agency	92	14%
EU institution/agency	43	6%
Academic or research institution	30	4%
Consultancy	25	4%
NGO	22	3%
Other	26*	4%
TOTAL	675	

**Including 12 legal practitioner, 8 non-EU government, 4 international organisation, 1 'various', 1 media.*

1.7.2 Participants in the break-out sessions

The break-out sessions were intended to keep a manageable group size for discussion, and with a view to ensure a balanced representation of stakeholder groups as far as possible, places were limited (total of ca. 125 across 6 parallel groups).

The Commission and project team applied consistent criteria to select which stakeholders should take part in the break-out sessions, with the main aim to ensure a balanced representation of stakeholder groups as far as possible:

- The following stakeholder groups were prioritised for the break-out groups:
  - Sectoral trade associations, Member States Competent Authorities (MSCAs), representatives from NGOs, academia, and EU agencies (ECHA, EEA, EFSA, etc). As we received registrations from over 150 different trade associations, we could only accommodate a proportion of these, therefore had to limit invitation in a way that aimed to achieve balanced sectoral representation (covering the pieces of legislation in the break-out sessions of the workshop, including chemical industry as well as downstream industries).
- The following stakeholder groups were not prioritised for the break-out groups, but are able to provide inputs through other consultation tools (e.g., open public consultation): non-EU stakeholders, individual companies (given their high number, i.e. 300+, and it was considered more efficient to include trade associations as they represent several companies within various sectors), consultants.
- The following stakeholders were allowed as observers (to listen to the debate and to provide clarifications if needed): EU institutions (ENV, GROW, SANTE, CLIMA, etc.), consultants involved in other Commission's studies closely linked to essential use (e.g. on generic risk management approach, authorisation, restriction).

For the above stakeholders prioritised, only one representative per organisation was allowed, except for Member State authorities, for which two representatives were allowed.

The stakeholder split for the break-out sessions (total for all groups) was as follows (calculated based on confirmed invitations): 47% for EU and Member State public sector (competent authorities and agencies), 32% for private sector, 13% for NGOs, 6% for academia, and 1% for international organisations.

2. Workshop content: morning session

2.1 Welcome

Patrick Child (Deputy Director-General DG ENV, European Commission) provided a welcome speech to begin the virtual event. This served as a reminder of the overall ambition of the essential use concept as an element within the wider Chemicals Strategy for Sustainability, to move to a more preventive regulatory framework which addresses the serious threat of pollution to people and the planet, by only allowing the most harmful chemicals to be used in exceptional cases where their uses are essential for society.

2.2 Overview of study objectives, approach and consultation

Kastalie Bougas (Wood) presented an overview of the overall objective of this project, i.e., to assist the Commission in the development and operation of an essential use concept to be applied horizontally in EU chemicals policy. More specifically, the tasks under the project are intended to deliver the following objectives:

- Screening to identify relevant existing EU chemicals legislation that already contain or will benefit from an essential use concept.
- Screening and mapping key stakeholders.
- Gathering and analysis of information, including an analysis of legislation, analysis of definitions and terminology across different legislation, and a review of additional information sources.
- 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.
- Conducting an impact assessment on the consequences of introducing the concept in REACH.
- Conducting a targeted stakeholder consultation including holding a stakeholder workshop.

Kastalie outlined that the project tasks are being supported by a broad stakeholder consultation. This includes: 1) questions on the essential use concept as part of the public consultation on the targeted revision of REACH, 2) input gathered from a range of stakeholders through this workshop, and 3) a targeted survey (to be sent to all organisations that attended the workshop) and up to 30 follow-up interviews with some stakeholders in affected sectors, stakeholders with expertise and interest in the topic, and relevant Member State authorities.

2.3 Essential use: fundamentals and definitions

To ensure a common understanding of the essential use concept and to avoid any misunderstandings or misinterpretations, Kastalie Bougas (Wood) presented an overview of the fundamentals and definitions underpinning the concept. In particular:

- The essential use concept is only intended to target uses of the most harmful chemicals[10], not all chemicals.
- The starting point for the criteria (as established in the Chemicals Strategy for Sustainability) indicate that essentiality of a use is defined by:

  1. 'The use is necessary for health and/or safety' AND/OR 'critical for the functioning of society'.

  AND

  2. There are no alternatives that are acceptable from the standpoint of the environment and health.

- The concept of 'essentiality' in this context should apply to the use of the most harmful chemicals and the technical function that they provide to a specific end use of a mixture / article / product / process / service. Determination of 'essentiality' will not be based on a consideration of whether the mixture, article, product, process or service itself is considered 'essential for society'.
- The assessment of essentiality is not permanent and may evolve through time.

Examples of aspects to consider were presented to provide more tangible meaning to the criteria (see Workshop slides in Appendix B).

The main elements to guide the application of the concept were summarised. These state that the essential use concept:

- Shall be usable for both generic and specific approaches to risk management.
- Needs to be applicable across relevant chemicals legislation, even though detailed implementation may vary.
- Shall focus on specific uses of chemicals and shall not be based on lists of products or sectors.
- Should not be based on a simple list of sectors or chemicals.
- Needs to be flexible to enable addressing emergencies (e.g. the COVID pandemic) or changing societal needs.
- Needs to ensure that the wider context (of the use of a chemical) is taken into account, in order to avoid regrettable substitution.

[10]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 (see FAQ document)

- Needs to be based on objective criteria and suitable processes, to ensure relevance for society as a whole.

2.4 Lessons learnt from the essential use concept in the Montreal Protocol and from legislation with similar concepts

Ian Keyte (Wood) presented some of the key research from the project on lessons learned from legislation which contains an essential use concept (or similar elements).

Three pieces of legislation were presented:

- The Montreal Protocol – As mentioned in section 1.3, this global agreement is the only existing example of the implementation of an 'essential use concept' in legislation. Under this agreement, the process involves nomination of essential uses by Parties to the Protocol, assessment of the nomination by the Technology and Economic Assessment Panel, and a decision on the derogation taken at the Meeting of the Parties.
- Biocidal Products Regulation – chemicals with certain properties (CMR cat. 1A & 1B, ED, PBT, vPvB, etc.) are subject to a blanket ban under Article 5 (1). Derogations exist which consider essentiality as per Article 5 (2), depending on: 1) active substance is essential to mitigate a serious danger to human/animal health or the environment, 2) not approving the active substance would have a disproportionate negative impact on society, and 3) availability of suitable and sufficient alternative substances or technologies. Article 55 also allows approval of non-approved active substances if the specific use is necessary to protect health or the environment / cultural heritage and there are no alternatives are available.
- REACH – While there is no explicit or implicit reference to an essential use concept currently within REACH, there are similarities in existing processes. For example, socio-economic analysis under restriction and authorisation could include considerations of criticality for the functioning of society and necessity for health or safety as part of the benefits of use (although this is not required, and benefits assessed are typically those to the applicant rather than society). In addition, both restriction and authorisation currently require an analysis of alternatives.

An overview of a number of pieces of EU legislation covered in this study, 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 existing 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	✓	-	✓

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

Key conclusions were presented as below:

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

Aspect	Key insights
Existing application of essential use	In addition to the Montreal Protocol, the concept of 'essential use' (or the components of the essential use concept as set out in the CSS) is included in some EU legislation. The main example is the Biocidal Products Regulation, but it is noted that a specific definition or criteria have not 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 authorisation or a derogation from restriction (e.g. based on a consideration of 'essentiality') in practice can be an onerous exercise (the process of collating data for assessing derogations is a time-consuming process) without a certainty of the outcome. Clearly set criteria for authorisations/derogations can therefore provide a better certainty as well as speed up decision making.

2.5 Criteria for essential use concept

Kastalie Bougas (Wood) presented the progress made under the project in elaborating criteria beyond the starting point from the Chemicals Strategy for Sustainability. This task involves building on lessons learnt from existing legislation (e.g., as above), insights from other relevant sources (e.g., academic and opinion papers), discussions with the European Commission, and inputs from stakeholders through the consultation activities. Kastalie presented the three proposed key phases in the essential use concept: 1) scoping, 2) assessment and decision, and 3) review.

The first stage is intended to systematically decide whether the essential use concept is applicable to regulate the use of a substance (the substance is considered one of the most harmful chemicals for which phasing out is a priority and the substance could be used in an article, product, process or service). Examples of relevant regulatory processes for the essential use concept include derogation from restrictions and authorisations under REACH, and the generic approach to risk management under broader chemicals legislation. It will be further defined whether essential use concept can be used under other legislation than REACH.

The second stage involves the assessment of essentiality: whether the use is necessary for health or safety or critical for the functioning of society and the assessment of alternatives. If both criteria are met (1. demonstrated necessity and/**or** criticality **and** 2. no available and acceptable alternatives), the specified use is deemed essential for society and therefore an authorisation or derogation from restriction is justified for a time-limited period to allow for the development and substitution to safe and sustainable alternatives. Risk management conditions are set to minimise the level of use, emissions and exposure to human health and the environment during production, use, and end-of-life and recycling.

The third stage recognises that the assessment of essentiality will evolve over time depending on technical progress on the availability of alternatives and changing wider societal needs. Therefore, essentiality of uses should be subject to reviews.

2.6 Questions and discussion points (Morning Plenary)

In this section, we summarise key relevant or recurring points during the workshop relating to the aspects covered during the morning plenary session. This includes:

- Scope of the essential use concept.
- Definitions and fundamentals.
- The criteria for determining if a use is 'essential' (e.g. based on criticality and/or necessity and assessment of alternatives).
- Flexibility of the criteria.
- The wider consultation and the break-out groups.

The inclusion of comments in this summary has been informed both by how frequently the comments or questions were raised in the chat and how relevant the themes are in the context of this study.

To reiterate – for specific questions or clarifications regarding the essential use concept, the Commission will provide responses separately at a later stage following this report.

Table 2.3 Key discussion points from morning plenary session

Theme	Comments
Scope of the essential use concept	• A key recurring point made was on the issue of if and how the essential use concept could operate taking into account the concept of 'safe use' e.g. through derogations from restrictions based on consideration of risk/exposure. • Some [industry] participants argued that in order to participate in this discussion appropriately, it is important to know how the essential use concept would be operationalised in the context of the generic approach to risk management (GRA) and other processes under REACH and what the interlinkages look like in practice.
Fundamentals and definitions	• One key aspect that participants requested further clarification about, was the definition of what 'use' is referring to in the essential use concept e.g. if this applies to substances or products or both? – see section 2.3. • For example, several [industry] participants questioned how essentiality of the use of a substance can be dissociated from the essentiality of the product or article (e.g. medicines raised as an example). • A large number of participants requested clarification on the definition of what 'most harmful chemicals' means in the context of the essential use concept – see section 2.3. • One comment from an [industry] participant noted that if the criteria/scope of what are considered 'most harmful chemicals' changes, it may then impact how the essential use concept would be applied in practice.
Essential use criteria (in general)	• Some [industry] stakeholders argued that proportionality should be included in the criteria, as a 'harmful' substance may be used in small quantities but could be considered 'essential' e.g. on the basis of having a large societal benefit. For example, some [industry] stakeholders argued that an important missing component of the presented essential use concept is a socio-economic assessment. • Some [industry] stakeholders noted that in some cases, a lot of end uses of substances are not known to suppliers or to authorities, making the assessment of essentiality more challenging e.g. where there are complex supply chains. • One [industry] stakeholder comment considered that the essential use concept should not apply to groups of substances, as many similar substances have many different uses.
Essential use criteria (assessment of criticality)	• Some [industry] stakeholders commented that the essential use concept is a wide-ranging concept and is clearly open for much debate so if an assessment of essentiality must come before a risk assessment, it is likely to be a complex, multi-step, multi-stakeholder process. • One [industry] stakeholder noted that when discussing administrative effort, it is important to clarify to whom the burden applies, e.g. authorities or industry. • Several [industry] stakeholders raised the importance of 'wider environmental' aspects in the criteria to assess essentiality, e.g. consideration if a substance contributes to the

Theme	Comments
	sustainability of a product or process, circular economy, renewable energy, energy efficiency, climate change mitigation etc.
Essential use criteria (alternatives)	• Following on from a point made by the project team during the plenary presentation, some stakeholders agreed that assessment of alternatives requires resources and time, and a very specific knowledge on the use and the technical function of the substance (which is knowledge held by downstream users of the substance in many cases, producers of articles). It was noted this can mean it is very challenging to make the process more efficient, especially where industry needs to do extensive testing to evaluate the suitability of alternatives. • A number of stakeholders raised that the loss of performance from using alternatives is an important aspect of the assessment and that further discussions will need to be held on what is the desired/adequate product performance. One stakeholder noted this is particularly important in military, national security and space applications. • As with the assessment of criticality, a number of stakeholders queried if 'wider' environmental criteria might be required e.g. consideration if alternatives support other objectives of the EU Green Deal, e.g. reducing CO_2, improving circular economy/sustainability, etc. • Similarly, some stakeholders recommended consideration of the full life cycle in the assessment of alternatives. • Stakeholders also warned against implementing criteria that could lead to potential regrettable substitution.
Flexibility of the criteria	• A number of stakeholders agreed that there needs to be a dynamic character of essentiality and several raised the point that there is a possibility that there are uses of a substance that are currently considered non-essential now but that becomes essential in the future. • It was noted there could be a risk of industry and/or R&D being externalised outside of the EU.
Wider consultation	• A number of participants asked for details on the next steps of the project and the additional consultation activities planned and how these are conducted (see section 4). • Many (more than 50) participants expressed their interest in being involved with the targeted survey as part of this project.

2.7 Break-out sessions - refining the criteria for the essential use concept

2.7.1 Overview

Break-out sessions were held to receive feedback from stakeholders in moderated group discussions, with a focus on how to refine the criteria for the essential use concept. The sections below summarise the key takeaways from this break-out session. These are categorised by

discussion point. Due to extensive discussions, we have aimed to specifically draw out key points of agreement or disagreement across the different break-out sessions and have presented these with specific reference to the discussion points covered, e.g., suggested answers to these questions. It should also be noted that differences in consensus between break-out sessions were observed.

2.7.2 Assessment of necessity for health and safety and of criticality for the functioning of society

1. Key elements required to assess if the use of a substance is necessary for health and safety

- Some stakeholders noted that the 'essentiality' of the function of a substance needs to be considered together with that of the end product/use (see Section 2.3)
- Industry, Member State authority and NGO representatives agreed that in some cases there will be a link between the essentiality of a use of a substance and the essentiality of the product it is used in. One stakeholder pointed out that the use of a chemical may be necessary in uses related to personal safety but considered non-essential in other uses.
- One NGO argued that the essential use concept should be used to allow the most harmful chemicals only in a very limited range of applications. Indeed, it was mentioned that trade-offs between safety and the environment may become apparent (e.g. protecting firefighters vs protecting the environment).
- However, some stakeholders raised the question if skipping risk assessment and socio-economic assessment would speed up the process of eliminating the most harmful substances compared to the existing mechanisms. One stakeholder argued that the essentiality concept is time consuming, and suggested it be used as a last resort.
- It was noted that when assessing the essentiality of a use of a substance, its ability to increase the longevity of the associated product should also be taken into account. Some stakeholders believed that some of the most harmful substances which can significantly prolong the lifetime of a product may be considered as necessary in some uses. In turn, they believed that derogations to restrictions for single-use products should be avoided.
- The issue of 'safe use' of substances was discussed between a number of stakeholders:
  - Trade associations and an NGO agreed that (in the context of cosmetics) the concept of safe use of substances is important in the regulation of chemicals. One trade association believed it is more important to establish if the substance is safe before considering essentiality.
  - While some stakeholders argued the essential use concept should not be applied in cases where "safe use" could be demonstrated (e.g. solders in electronic devices, which do not come into human contact after assembly), others challenged this as they believed that the whole life cycle of the substance must be considered, including the waste stage and recycling process, which would allow accounting for both human health and environmental concerns.

- One NGO, however, believed that the assessment of essentiality should not start with a consideration of safe use before coming to an essentiality consideration as it would slow down the process. Another participant from academia/research added to this that safety is failing, which is why there is a need to look at the essentiality of the use before considering whether the use is safe. Instead, they highlighted that it could follow a similar process to the derogation from restrictions (for CMR substances) under the Cosmetic Products Regulation (CPR) as industry already knows the criteria that have to be met. One trade association highlighted that industry already spends large amounts of time compiling safety data.

2. Key elements required to assess if the use of a substance is critical for the functioning of society

- Several stakeholder groups questioned the advantage of the concept compared to the socio-economic analyses already done under REACH and pointed out that it is not clear how the concept would improve or make processes faster.
- The example of roller coaster brakes was used to point out that the criticality of the use of a substance should be assessed, not the final product. This was subject to a vivid discussion among the stakeholders, as some said that this was difficult to separate the use of the substance from the use of the final product in many cases, and some argued that indeed also the criticality of the final product should be assessed. Indeed, one authority representative criticised that it is not the criticality of the use of the substance in a product/article that should be considered, but the criticality of the whole product for the functioning of society.
- Further to this, one trade association argued that it is important to consider the performance of the substance for the functionality of the end product. A similar notion was shared among other Member State authorities where they agreed that the role of the end product in the society should be considered to decide the criticality of the substances used in its makeup.
- One element brought up by Member State authorities is the sustainability of phasing out some harmful chemicals as it may affect the efficiency of some products. Indeed, a trade association raised a point on how the criticality of the use of a substance could be related to its role in fulfilling another policy goal to protect the environment. For example, the performance of the substances that enables low temperature washing decreasing energy usage, so fulfilling the Green Deal criteria as well.
- One trade association raised the example that some components of fuel additives might be SVHCs, but their use in a product (i.e. the fuel) that contains them could be seen as critical to the functioning of society. They had concerns over the unknown, downstream effects of considering derogations from restriction for substances based on the essential use concept, for example where the supply is quite complex and difficult to trace.
- One argument was raised to state that we should avoid making decisions on derogation from restriction of substances that are key for innovation based on the essential use concept. The essence of the argument was that we should not restrict

chemicals that can lead to the development of society and that we should consider these chemicals when they are being used towards research and innovation.

- A number of additional discussion points and questions were raised by stakeholders during this part of the break-out session, including:
  - One trade association reflected that we might get a scenario where it is not commercially viable to produce a substance just for the essential uses.

3. Key elements concerning cultural heritage aspects to be considered in the decision on whether the use of a substance is critical for the functioning of society

- One stakeholder pointed out, that cultural heritage aspects were a vague point in what they called a vague concept and suggested that the term should be avoided.
- It was noted that for cultural aspects, consumers should be involved in the decision-making process.
- A stakeholder from academia/research noted that for cultural aspects the use of a substance is not looked at, but rather the product is regarded – the example of sports cars and their red paint was given. This same stakeholder remarked that a difference should be made between what is nice to have and what is essential to have.
- One stakeholder stated that looking at cultural heritage aspects in the essential use concept could lead to serious distortion of the market, if this was not decided on a Union level, but Member State level.
- Some members of the trade associations pointed out that some substances are essential for religious purposes but pose a risk to human health.

4. Application of the essential use concept (in the context of assessment of necessity for health and safety and of criticality for the functioning of society)

- It was noted that specific cases from the REACH authorisation process provide good examples and should be looked at further, e.g. uses of substances included in Annex XIV applied for or not applied for anymore after the sunset date may provide an indication of what is essential for industry or not. The project team noted that illustrative case studies will be developed as part of this work and further stakeholder input will help develop these (see Section 4).
- The possibility of clustering uses of substances, and therefore making evaluation of criticality/necessity and alternatives easier, faster and more cost-effective was raised.
- One Member State authority stated that the criteria for the essential use concept are not yet defined in a way that allows relevant discussions and some stakeholders pointed out that it is not clear in which cases the essential use concept should be applied. There was a clear consensus among trade associations, EU agencies, and Member State authorities on the need for the clarification of definitions (e.g. safety) and criteria along with agreeing on one definition for each term.

- Two trade associations indicated that there needs to be greater stakeholder involvement in the assessment of essentiality. However, one Member State authority indicated that there are many opportunities for stakeholder involvement and that the decision ultimately needs to be a political decision.

Additional comments

A number of additional discussion points and questions were raised by stakeholders in the break-out sessions that did not directly relate to the specific discussion points outlined above, including:

- The issue of who will actually make decisions regarding what is considered 'necessary for health and safety' was raised by a number of stakeholders.
- One stakeholder pointed out that, concerning the use of substances in medical products, there needs to be good coordination between the essential use concept and already existing exemptions for certain chemicals regarding the medical sector. One academic stakeholder said that some specific sectors could be exempted entirely from the application of the essential use concept such as pharmaceuticals, as the sectors themselves could be considered essential.
- A representative from a Member State authority stated that there are many substances uses for which no request for authorisation under REACH has been made. It was suggested this can be taken as a starting point to see what industry considers essential or not.

Key data gaps

- Stakeholders argued that, in order to understand the essential use concept, there is a need for further clarity and granularity in the definitions. For example, the definitions of "health" and "safety" must be very clear.
- The steps in the application of the essential use concept need to be clearly defined.
- Some trade associations shed light on the importance of considering other applications beyond the ones stated in the background document or slides, such as mental health and well-being. They believed that substances used towards making any product that improves the wellbeing or mental health of the society should be considered necessary. On that notion, there was a suggestion to make a list of what is considered necessary for health/safety to be applied horizontally across all legislation.

2.7.3 Assessment of alternatives

1. Key elements required for the assessment of acceptability of alternatives from the standpoint of the environment and health

- Some stakeholders again raised the point that there should be an exemption for substances whose use could be demonstrated to be safe, which could be assessed in a separate step before evaluating the essentiality criteria (criticality/necessity and alternatives). Other stakeholders argued that, when considering alternatives the whole

lifecycle needs to be considered, and then "safe use" would be seen differently, as the "most harmful substances" often cause problems in the waste / recycling stage.

- Some stakeholders said that there are several levels of "alternatives", i.e. not only chemicals with the same function, but non-chemical alternatives. All of them should be considered. This was supported by several stakeholders. It was also noted by one stakeholder that historical/traditional solutions should be taken into consideration for alternatives (e.g., bees wax instead of cling wrap, or paper instead of plastic packaging), as new alternatives might have unknown risks associated with them.
- It was stated that a lack of alternatives can spur innovation and highlight areas where research needs to be done; however, when creating something new, new possible risks may also be created. An NGO indicated that a timeline on the derogations to restrictions under the essential use concept should be provided to give industry time to develop alternatives.
- One key aspect is the need to consider holistically the range of factors i.e. technical feasibility as well as risk from alternatives to human health and the environment when looking at alternatives (and e.g. what loss of performance would be acceptable).
- It was highlighted that there is also a need to consider cases where 'most harmful chemicals' are only used in industrial processes, but not present in the final products. In certain industry sectors (e.g. pharmaceuticals) the industry is already regulated and the 'most harmful chemicals' are often not present in the final products. It was suggested that such sectoral legislation (as well as e.g. RoHS, POPs) could be taken into account.
- A Member State authority stated that the hazard assessment of alternatives should demonstrate that there are "lower hazard" alternatives (to complement considerations of the technical feasibility and efficiency of alternatives). An NGO responded that lower hazards can also be unacceptable and that degradability, bioaccumulation, persistence, PBT, vPvB etc. in the whole life cycle should also be considered to avoid regrettable substitution. Another stakeholder agreed with this and stated that lower hazards can also be considered unacceptable and requested a wider discussion on the risk of alternatives within the same substance/chemical group (e.g. Bisphenol A vs. Bisphenol B). In this context, a remark was made from an NGO that alternatives should not be subject to harder scrutiny.
- There was no consensus on how risk assessment should be considered within the assessment of alternatives. Some argued that assessment of alternatives should be based on risk, while others suggested to stick to a hazard assessment.
- Several stakeholders agreed on the importance of the environmental consequences of alternatives alongside their "safety" for human health with no specifically opposing comments made by other stakeholders. Stakeholders argued that there is a need for a proper environmental impact assessment.
- Multiple stakeholders from industry and Member State authorities agreed that the assessment of alternatives should include economical and energy consumption aspects in addition to environmental and health aspects.

- Stakeholders believed that the whole lifecycle of the substances should be taken into account (i.e. how is it sourced, does the processing require large amounts of energy etc.). In one group, one Member State authority indicated that energy/material consumption etc., as well as the emissions dynamics, should be included in environmental considerations of alternatives and the importance of this was agreed upon by one academic or research institution.
- Some stakeholders considered that it is key that a consideration of the health and safety 'performance' of alternatives is better included within the definition of safety for the essential use concept. It was stated that safety for some products is dependent on their technical performance being of the highest level and that performance can drive personal safety.
- There was a discussion on the extent to which consumer preference should be considered when discussing performance. One trade association highlighted the need to avoid regrettable substitutions when applying the essential use concept, noting the example of a previous move away from endocrine disruptors in products, towards use of allergens.
- One key area of discussion centred around the issue of 'loss of function' or the required level of performance of the alternatives. One trade association and one NGO indicated that the level to which a compromise on functionality could be made depends on the substance (and its use). It was noted from the discussions that in some cases, there can be no loss of performance tolerated (e.g. due to specific legal standards to be fulfilled) while in some cases, high performance is not needed for the final product. One NGO noted in this sense that one needs to establish what an acceptable loss of performance should be, in consideration of the function of the product. One trade association stated that this is a societal question, and will reflect expectations of consumers. One NGO indicated that consumer acceptance depends on the amount of information they are given.

2. Key steps in the assessment of alternatives

- One trade association and one academic or research institution stated that the current processes for the assessment of alternatives under REACH could be a good example for the assessment of alternatives under the essential use concept.
- There were differences of opinions regarding the order in which evaluation of assessment of criticality/necessity and assessment of alternatives should be undertaken. Some stakeholders considered that this should be decided on a case-by-case basis, so that "whichever is fastest / easiest" should be done first. In another group, there was general agreement that steps 1 (the assessment of criticality and necessity) and 2 (the assessment of alternatives) are in the right order. Some stakeholders from other groups (and the plenary session) did not entirely agree necessarily.
- It was highlighted that a claim to have an alternative must be backed up with proof with regard to a sufficient level of performance and accessibility to other sectors than sectors for the specific use in question.

- One industry association representative stated that if a substance is substituted, one should consider several other aspects like e.g. resource efficiency and waste generation. Another industry association underlined that a lower performance of alternatives might require use of a higher amount of the substance. Therefore, they suggested a 'wider environmental assessment' covering these aspects.
- A stakeholder also voiced the opinion, that a proportionality assessment, which includes socio-economic considerations, would be beneficial.
- One NGO proposed that the assessment of alternatives could be designed to allow a wider range of companies to offer their chemical/non-chemical alternatives to the substance in question – e.g. the process could involve an open tender, which would request a specific function and state the funding that can be provided. A trade association agreed to an extent but indicated that alternatives need as deep a scrutiny as the alternative assessment provided by original applicant for the essential use. The NGO suggested that if an alternative would not be developed within specified timeframes, a condition for authorisation could be to finance the alternative in the review period. They highlighted that the alternative might then be available when next assessed.
- A trade association indicated that an applicant that wants a derogation with an analysis of alternatives for an essential use, should follow a process that is transparent in which other stakeholders (e.g. manufacturers/suppliers) can give alternative suggestions, as the original applicant may not have all the necessary information.

3. Which actor(s) should provide information/evidence on alternatives, and in what format?

- It was agreed by several stakeholders that the applicant for derogation to restriction/authorisation should provide information on alternatives. An authority representative suggested that industry should provide information on alternatives first because they have the information. Others agreed and stated that industry stakeholders and manufacturers should provide information/evidence on alternatives, but also that users should contribute too. A Member State authority highlighted that not only the producer of substances should have to provide the information, but industry as a whole should pitch in for the assessment of alternatives.
- Stakeholders pointed out that the assessment of alternatives should involve industry (e.g. product manufacturers), as these are the most likely to have the most knowledge about possible alternatives. A representative from a trade association remarked that experience has proven that it is very difficult for actors others than industry to perform an analysis of alternatives. Companies are the best placed ones to know what the expectations/requirements from their consumers are.
- Stakeholders queried if just the applicant would need to provide information on alternatives and noted issues of verifiability if there is information, for example, from only one supplier of potential alternatives. Issues with sharing of confidential business information (CBI) were also raised in some groups.

- Some trade associations remarked that it may be challenging to properly assess the validity of the assessment when it comes to alternatives, and that the industry has to assess the end product's functionality with the new alternative. Some NGOs believed that there should be a separate entity that researches the possibility of other alternatives and their feasibility to avoid the bias of each industry.
- Caution was urged against cases where a single competitor can provide (perhaps unverifiable) information. Industry (applicants) will not provide information on all alternatives, so the process would need additional actors looking at the wider market and availability of alternatives.
- An NGO stated that proof should be presented to show that there are no acceptable alternatives and that the decision should include several stakeholders (e.g. involving a public consultation).
- One discussion point was that it is critical to understand who has the authority for decisions on the 'suitability' of alternatives. It was stated that some products are single use and that it appears difficult to assess the performance of alternatives in these products. It was also noted that for some products, this cannot be done on the substance level.
- Some stakeholders indicated that the existing evaluation / consultation for assessing alternatives may be insufficient and that new ways should be considered. They highlighted that a platform for an exchange between regulatory authority/agency (e.g. ECHA) and industry could be useful to facilitate this. Indeed, a trade association suggested that confidential business information should be shared when it comes to finding an alternative.

4. Key lessons learnt from analysis of alternatives under REACH and other legislation

- An industry associate stated that the assessment of alternatives is already done in the REACH processes and questioned the sense in changing the existing process and establishing a new process. In one group, a trade association and an academic/research institution also indicated that the authorisation process of REACH already has an analysis of alternatives that works well.
- There was a general consensus that regrettable substitution should be avoided when assessing alternatives. An NGO representative stated that the grouping approach to substances should be included in the analysis of alternatives. An industry representative emphasised however that this should not apply to the functionality of a substance (e.g., plasticiser) but only a substance group. It was argued that the definition should not be too narrow as to avoid the exclusion of viable alternatives and the hampering of innovation.
- An industry representative stated that the knowledge gained from the analysis of alternatives could be accumulated and documented. This could encompass the hazard classification and the functionality of the substance (e.g., flame retardant, plasticiser etc.). This way, one can look at such a list when looking for an alternative to a substance and as such save resources in the assessment.

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- An individual stakeholder indicated that we must question what the level of performance needed from the alternative for the function is and how much performance is lost through non-approval of authorisation or derogation from restrictions. They believed that it must then be assessed whether an appropriate level of performance is still met and what the consumer preference is. It was mentioned by a different stakeholder that consumers might accept a lower performance/functionality if they know that the product does not contain hazardous substances (anymore). For this the consumer needs to be informed, which can be done via a label on the product or packaging.
- One trade association indicated that there are issues related to cost and competition relating to alternatives. For example, they stated that if you provide a commodity chemical that is non-essential and replace with alternative that is expensive, this will potentially have societal impacts.
- One stakeholder believed that some guidance is needed on what level of costs (to industry, society etc.) would be acceptable following the non-approval of authorisation or derogation from restriction of a substance.

5. Application of the essential use concept (assessment of alternatives)

- Some stakeholders believed that the assessment of alternatives is quite clear as it is already part of many legislations (e.g. RoHS).
- An authority representative suggested that criteria should be provided for the term "availability".
- Stakeholders in one group indicated that not only should there be evidence that alternatives exist, but also that these alternatives are suitable and work reliably under real-life conditions. They indicated that this is extremely crucial in safety applications (e.g. cars) which have a long lifetime and where small but significant "degradation" may happen during the long service life of the final product.
- One trade association highlighted that an alternative needs to have a certain level of advancement to show that it is a viable alternative.
- Industry stakeholders said that the long time taken to develop alternatives should be taken into account in an assessment of alternatives and stated that an assessment of alternatives needs a sufficiently long timeline on it to account for this. Indeed, one trade association noted that it is not easy to substitute a substance without going through a process to confirm feasibility/acceptability for the new substance in the end product. This argument was supported by an EU agency that stressed that the time it takes to develop an alternative, along with the availability of alternative, should be included in the assessment of alternatives.

Furthermore, industry stakeholders stated that for each use, the re-assessment of the essentiality after it was first decided should be adapted to these (i.e. sufficiently long) timelines to avoid unnecessary costs.

Key data gaps

- Stakeholders pointed out that clearer definitions for “safety”, “health and safety", “chemical safety”, “functioning of society”, “non-chemical alternative” and more are needed. Some stakeholders stated that the definition of “acceptability” should cover suitability, technical performance, stability and lifetime, etc. Additionally, stakeholders highlighted that a list with necessary key functionalities (e.g., flame retardancy, plasticiser etc.) could simplify the analysis of alternatives.
- A member of a trade association highlighted the fact that there is difficulty in identifying alternatives that have the same level of performance.

3. Workshop content: afternoon session

3.1 Feedback from morning break-out groups

The workshop resumed with short presentations from the moderators and rapporteurs of each break-out group to summarise the key arguments and takeaways (as synthesised in the above section of this report).

3.2 Welcome

Kristin Schreiber (Director DG GROW, European Commission) provided a welcome and introduction to the afternoon session, giving an overview of the aims, i.e., to discuss how the essential use concept can be applied in specific legislation, including REACH, the Cosmetic Products Regulation, the Toy Safety Directive, the Food Contact Materials Regulation, and the RoHS Directive.

Kristin also revisited the wider context of the essential use concept, including the reasoning as to why the concept could improve existing procedures to decide on the justification of derogations from restrictions or for authorisation of otherwise banned substances. For example, within REACH, there are current procedural limitations due to the long and heavy scientific and technical assessment of benefits and risks which can lead to unnecessary delays in decisions, as well as the difficulties in quantifying some elements of the socio-economic analysis, in particular, the societal impacts.

3.3 Legislation that could benefit from essential use concept

Ian Keyte (Wood) presented the approach to assess legislation that may benefit from the essential use concept. The project team has so far completed a first assessment based on a screening of EU legislation, to identify a list of key pieces of legislation that could benefit from the concept. As a result of this screening, the following pieces of legislation will be considered in the analysis (pending confirmation from the Commission):

- REACH.
- Cosmetic Products Regulation.
- Safety of Toys Directive.
- Food Contact Materials Regulation.
- Restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS) Directive.
- End-of-life vehicles (ELV) Directive.
- EU Taxonomy.
- Biocidal Products Regulation.
- Plant Protection Products Regulation.

For each of the pieces of legislation taken forward, the project team will: propose possible broad policy options; highlight whether adaptations need to be made when applying the horizontal essential use concept to other pieces of legislation (if any), and; highlight key changes / nuances required in policy options for each piece of legislation. This will rely on desk research and consultation with stakeholders and desk officers at the Commission.

3.4 Policy options for essential use concept in REACH

Kastalie Bougas (Wood) presented on the first considerations for developing policy options in REACH.

The concept is intended to be applied within the processes of authorisation, derogation from restriction, and generic risk management approaches. Overall, options should be developed to:

- Contribute to reductions in the use, and consequently the emissions, exposures, risks and impacts associated with most harmful substances, by facilitating the phase out of non-essential uses.
- Minimise the need for time-consuming and costly assessments for uses of the most harmful substances that are non-essential for society.
- Allow systematic decision-making and improve consistency in the assessment of uses of the most harmful substances, including with legislation other than REACH.
- Introduce more simplicity, transparency, predictability, and efficiency to prevent uses of the most harmful substances that are not necessary or critical (in terms of health or safety and/or the functioning of society) and where there are available alternatives acceptable from the standpoint of environment and health.
- Provide more regulatory certainty to businesses and preserving integrity of the internal market and competitiveness of EU businesses.

The following parameters have been identified to inform variations of policy options to apply the essential use concept within REACH:

- The use (or not) of an initial screening for alternative products available on the market in the same product category that do not contain the most harmful substances to quickly filter out non-essential uses, with a view to shorten the decision-making process.
- The use (or not) of an initial screening of criticality / necessity to quickly filter out non-essential uses, with a view to shorten the decision-making process.
- The use (or not) of fallback mechanisms for emergency and crisis.

The options will be compared against “Option 0 - do nothing” (the baseline).

Further work on developing options will involve clearly describing the policy options in the context of the wider REACH revision, identifying actions which would need to be undertaken by various stakeholders under each option, and drawing out information on the underlying logic behind the options including the key differences between each option and the baseline. This will also be informed by ongoing discussion with the Commission and stakeholders. Changes in the options

may be expected based on the received feedback, for example, whether any other elements should be considered.

3.5 Approach to impact assessment

Kastalie Bougas (Wood) described how the development of policy options (above) would feed into an impact assessment undertaken by the project team. This will include an identification of the possible impacts of policy options and a prioritisation of the most significant ones for in-depth assessment. Specific details of the type of costs and benefits to be considered in this assessment are provided in the workshop presentation slides (see Appendix B).

Expected costs to be covered include direct costs (e.g. capital and operating expenditures, administrative burden, monetary obligations, hassle costs); enforcement costs (e.g. monitoring costs; and indirect regulatory costs (e.g. increased / decreased costs to consumers, substitution of inputs/ products/services).

Expected benefits to be covered include environmental, economic, and social (health) aspect.

Options will be compared through a qualitative analysis in complement to a quantitative / semi-quantitative cost-benefit analysis, including cost assessment, benefit assessment, and approaches to deal with gaps and uncertainty (extrapolation uncertainty and data uncertainty).

3.6 Questions and discussion points (afternoon plenary)

In this section, we summarise key recurring or frequently made points during the workshop relating to the aspects covered during the afternoon plenary session. This includes:

- General aspects on operationalisation.
- The essential use screening steps.
- Application in other EU legislation.
- Impact Assessment.

To reiterate – for specific questions or clarifications regarding the essential use concept, the Commission will provide responses separately at a later stage following this report.

Table 3.1 Key discussion points from afternoon plenary session

Theme	Comments
General aspects on operationalisation	• Several stakeholders queried how legal certainty and continuity can be guaranteed for industry and without hampering innovation and investments. It was warned that if R&D is moving outside the EU, then production might follow. • Several stakeholders raised the issue of how SMEs with little resources and knowledge can comply with the requirements involved with requesting derogations under the essential use concept.

Theme	Comments
Essential use screening steps (for REACH)	• One stakeholder comment noted that the flow chart presented during the plenary session ends only with the two extreme outcomes of banning a use or giving a derogation to restriction, arguing this should also include evaluation based on wider socio-economical aspects and other benefits. • Several stakeholders warned (as noted above) that the complexity and time requirement of an assessment of alternatives is being underestimated. Some expressed doubts that "screening" will be enough for an informed decision and a detailed analysis will have to follow, which potentially increases the complexity and does not necessarily make the process easier or faster.
Application in other EU legislation	• Some industry associations queried the application of essential use concept in the Taxonomy legislation, and expressed scepticism if this can be applied in practice. • One stakeholder comment noted that the 'lessons learned' from other legislation is missing specific important product legislation such as the EU Medical Device Regulation (MDR) that addresses the use of CMR substances.
Impact Assessment	• Several [industry] stakeholders warned that EU manufacturers may not chose to produce substances that are only required for limited essential uses. This could lead to importing from jurisdictions where there are no such market constraints. This raised the question of whether loss of competitiveness needs to be considered in the impact assessments of the essential use concept. • One stakeholder comment considered that a full impact assessment for essential use concept is still required and essential use concept should be assessed holistically in line with GRA, overall reform of risk management, ongoing legislative reviews etc, to test if the essential use concept does make things more effective and efficient. • One suggestion by one [industry] stakeholder was to run some real life pilot test case(s) to assess its practicality and consequences.

3.7 Break-out sessions - Policy options for REACH

3.7.1 Overview

Following the plenary, a breakout session was held to receive feedback from stakeholders in moderated group discussions to focus on the definition, scoping and feasibility of policy options for operationalising the essential use concept in REACH.

The sections below summarise the key takeaways from this breakout session, categorised by discussion point. Due to extensive discussions, we have aimed to specifically draw out arguments which were emphasised across breakout sessions and those which related most closely to the discussion points, e.g., suggested answers to these questions. It should also be noted that differences in consensus between breakout sessions were observed.

3.7.2 Key takeaways

The breakout session on the policy options for the essential use concept in REACH covered three main discussion points. We summarise the main talking points across the different breakout sessions as follows:

1. Feasibility and usefulness of screening steps

- The main arguments for screening uses of substances in terms of their criticality for society and their alternatives were that these screenings could help save time and resources. NGOs, for example were largely in favour of implementing these screening steps within the essential use concept.
- Conversely, the main arguments against a screening step were that it is too time consuming, overly complex, infeasible, and should be replaced by a detailed assessment of alternatives. Trade associations mainly made these arguments.
- One of the views expressed was that in order to integrate the essential use concept into REACH, there is a need for further scrutiny, and to consider the benefits and drawbacks of different options beyond preliminary screening.
- Another view (from a Member State authority) called for a flexible approach and the possibility to decide for each individual case whether the screening should be done first for criticality/necessity or for alternatives.
- A key suggestion was that the safe uses of a substance could be screened before assessing the criticality of the substance or its alternatives. This may prevent the criticality and alternative screenings from removing safe uses of chemicals.
- NGOs and academic research institutions agreed the essential use concept should be part of the risk management process with the authorisation and restriction processes, rather than be assessed in isolation. This may result in a smaller amount of uses which need to be screened by the essential use concept.
- The main argument in favour of the assessment of alternatives being considered first is that the research and development of an alternative takes years in some sectors, and we need an upfront guide on what alternatives to assess. The examples of the lipstick case or of microplastics in cosmetics were alluded to, to note that there may be very straight-forward cases for which a conclusion on alternatives can be made quickly, without needing to go through the whole process. Another argument made by a Member State authority stipulated that from experience, alternatives require more in-depth assessment, meaning the criticality screening process should be first.
- A key argument against the assessment of alternatives being considered first is that a fast screening of alternatives can be based on incomplete or inaccurate information, leading to alternatives that are not appropriate for the considered uses.
- A Member State authority participant remarked that it should be considered on a case-by-case basis whether if a conclusion is made on the necessity or the criticality of the use, there is a need for analysing the alternatives, and the other way around.

- Another argument was that the order of which screening should come first should be flexible and depend on the information available. In line with this, an EU agency participant proposed implementing a tier assessment that would look first at the criteria that are clearer and more easily accessible, then at those more time or energy demanding.
- A discussion took place again around the concept of safe use. Industry associations insisted that if a use is safe, it should not undergo an assessment about its essentiality. In response, a number of participants argued against the concept of safe use, in particular if in relation to the most harmful substances. To illustrate this, it was noted that in the authorisation process, most cases so far have followed the socio-economic route, not the adequate control one. An allusion was made to pesticides, where the consideration of safe use does not take into account the whole lifecycle of the substance, or to PFAS, a group of "forever chemicals" that keep cumulating in the environment.
- A trade association argued that new approaches to chemicals management under the revision of REACH should be proportionate. Indeed, some substances are used in very little quantity in large number of products, so redesigning products cost may be more than the benefits associated.
- There was a broad agreement that a key challenge for screening might be the accessibility and availability of data necessary to carry out a proper screening, which industries sometimes find hard to provide (e.g. seen in PFAS restriction).
- A Member State authority representative proposed that the assessment of essentiality should not be mixed with socio-economic considerations.

2. Information requirements for proving that a use is essential

- In addition to assessing whether alternatives exist, there could be an assessment of the suitability and availability of these alternatives. This can be done using indicators such as the production volume of alternatives.
- Several stakeholders including NGOs agreed that the process of screening a use of a substance for its essentiality for society needs stronger information requirements to provide more information to authorities. Requesting downstream users to provide information on alternatives was a suggestion to achieve this. A nuance was (by an NGO stakeholder) made between passive information tools, i.e. information that industry is supposed to have on the use, the function and the volume of the substance, and active information tools, i.e. information sought by authorities.
- Another suggestion was that the timeframe for the consultations on the different criteria of the essential use concept should be longer than the current consultation processes under REACH, to allow sufficient time to develop and share this information.
- Several Member State authorities pointed out that anything below the protection level imposed by current legislations is not acceptable, therefore, the implementation of less strict regulation on chemicals is not possible.

- An argument against qualifying uses of substances as essential early in the regulatory process is that some industries would be discouraged from investing in R&D to find alternatives.

3. Feasibility/usefulness of a fallback mechanism for emergency situations

- A number of stakeholder groups agreed that there is a need of a fallback mechanism in case of an emergency (e.g. the case of COVID-19 pandemic was made as some substances were allowed for surfactants use e.g. under the BPR). A fallback mechanism would allow for the possibility to remove a derogation after it has been granted in case of an emergency. However, there was some disagreement regarding whether there needs to be additional mechanisms put in place under REACH.
- Stakeholders against a dedicated procedure for emergency situations argued it would be a distraction at this stage and is not necessary if everything works well, since it would otherwise add complexity to the process. Rather, they prioritised a need to focus on the functioning and efficiency of the essential use concept first. A representative from a Member State authority noted that there are regulatory processes in REACH that allow the Commission to take action if needed.
- One stakeholder argued that it should be possible to quickly revert back to the use of the original substance, if the alternative fails, which may only be discovered some years after it was implemented.
- An academic research institution and a trade association agreed that REACH can be flexible and adapt and did not believe a change is needed in respect of a fallback mechanism.
- An NGO highlighted that the criticality of a use of a substance should not preclude individual Member State authorities or the Commission from taking part in emergency measures.
- One industry representative argued in favour of introducing such a mechanism in REACH, since Article 2(3) is only related to national defence and Article 129 (the standard clause) is limited to MS initiative.
- One Member State representative stated that a fall-back mechanism could be beneficial since conditions taken into account when deciding on essentiality may change in time.

Additional comments

A number of additional discussion points and questions were raised by stakeholders during this part of the break-out session, that did not directly relate to the discussion points above, including

- A Member State authority argued that the consequence of not being granted an authorisation or derogation from restriction for a certain use should be taken into consideration when assessing the criticality.

- It was broadly agreed between different stakeholder groups that it is important to anticipate how the consumer or producer may react if a use of a substance is considered non-essential and therefore not approved for authorisation or derogation e.g. if it means a substance or product is no longer available to them. There is a need to be weary of unregulated alternatives.

3.8 Break-out sessions - policy options for other EU legislation

3.8.1 Overview

A second breakout session was held to receive feedback from stakeholders in moderated group discussions to focus on the definition, scoping and feasibility of policy options for operationalising the essential use concept in various pieces of legislation.

Each breakout group focused on one of the following pieces of legislation:

- REACH (two breakout groups continued the discussion of the first breakout session, the points from which were merged into the above section).
- Toy Safety Directive.
- Cosmetic Products Regulation.
- RoHS.
- Food Contact Materials Regulation.

The sections below summarise the key takeaways from this breakout session, categorised by legislation type and discussion point. Due to extensive discussions, we have aimed to specifically draw out arguments which were emphasised across breakout sessions and those which related most closely to the discussion points, e.g., suggested answers to these questions. It should also be noted that differences in consensus between breakout sessions were observed.

3.8.2 RoHS Directive

Benefits from essential use concept in this legislation

- Stakeholders agreed that the RoHS legislation already contains many aspects of the essential use concept.
- An industry stakeholder highlighted, that a horizontal essential use concept would increase coherence and harmonisation across adjacent legislations. This would e.g., strengthen the coherence between RoHS and the ELV Directive, which was seen as a benefit.

Feasibility

- Many elements of the essential use concept are already found in RoHS, hence the incorporation of a horizontal essential use concept was seen to be achievable.

- However, some stakeholders from industry and authorities cautioned, that changing the currently well working system requires attention to detail to avoid negative impact on the efficiency of RoHS.
- Industry and NGO stakeholders cautioned that decisions on the use of the most harmful substances and their alternatives should rely on solid data, i.e. harmonised classifications and reviewed assessments.
- Industry stakeholders brought forward the idea of clustering uses of substances in the assessment of essentiality, as this might help increasing the efficiency of the concept and speeding up decisions.

Flexibility in criteria and feasibility/usefulness of a fall-back mechanism for emergency situations

- Member State authorities noted the flexibility of the current mechanisms under RoHS (regular review, with stakeholders able to apply for granting or removing derogations). The stakeholders discussed, if and how the existing flexibility should be preserved while also providing the certainty required by industry as basis for investment choices.
- Also, the required flexibility concerning the review was discussed, and stakeholders pointed to different aspects. On the one hand, intervals too short would lead to high costs (assessments, uncertainty), while intervals too long would provide an incentive against the development of alternatives, therefore working against the aim of the essential use concept.
- Industry stakeholders urged the incorporation of a fall-back mechanism for cases in which alternatives fail after some time in daily use. It was pointed out, that due to long service times of products regulated under RoHS, an alternative first deemed suitable could fail after years, possibly with severe consequences. Then, it should be possible to revert quickly to the use of the initially substituted most harmful substance.

Coherence with other EU legislation

- There was consensus that increased coherence with adjacent legislation, e.g., ELV, would be beneficial, and that the essential use concept may lead to such harmonisation.
- However, stakeholders cautioned not to hastily overwrite the specifics of the RoHS legislation.

3.8.3 Cosmetic Product Regulation (CPR)

Benefits from essential use concept in this legislation

- In terms of potential advantages, one Member State authority representative noted that where risk assessment is problematic, the essential use concept could be useful for this legislation e.g. for substances where there is no clear toxicological threshold. However, they indicated that 'suitability' of alternatives is not defined in the CPR so needs to be defined in the essential use concept.

- One industry association noted that CMR substances are already banned and these are the substances mostly looked at under the essential use concept. Another highlighted that for cosmetics, everything comes back to safety of uses rather than essentiality.

Feasibility

- One NGO noted that Article 15 of the CPR has stricter criteria than would be applied under REACH as there is the requirement to comply with food safety legislation. They considered that it is unlikely that such requirements would be transposed into the REACH regulation. This has, therefore, raised the question of how REACH and CPR will interact when applying the essential use concept.
- It was highlighted that on the human health side, uses in cosmetics are not covered in the chemical safety report under REACH, meaning the essential use concept within the CPR would then apply. However, for the environmental aspects regarding cosmetic products, the essential use concept within REACH would apply.
- One Member State authority noted that cosmetic products are covered by REACH for environmental aspects and that the introduction of the essential use concept should have the same approach for both legislations. They followed-up on this by stating that the essential use concept would assess potential derogations from restrictions based on essentiality for society under REACH but also on risk for the user under the CPR.
- One trade association queried whether criticality and necessity could be assessed in terms of what substances used in cosmetics do for society rather than having knock-out criteria. They indicated that a high level of safety is needed in cosmetic products which should not apply in what was described as "a generic way" under REACH. This stakeholder believed that non-approval of authorisation or derogations from restriction for safe uses of the most harmful chemicals in cosmetics would be disproportionate and beyond the requirements of the CPR.
- An NGO stakeholder noted that there is no socioeconomic assessment in CPR whereas there is for some processes under REACH, and that the safety concept in the CPR is different to REACH. They requested that these need to be taken into account when implementing the essential use concept.
- A trade association stakeholder stated that currently there is a fixed timeline under the CPR for derogations to restrictions (15 months). This association stated that if the essential use concept is added, then a clear timeline must be given and 15 months would not be possible.
- One NGO stakeholder stated that when derogation cases under Article 15(2) occur (which have been few), what has been missing are questions like "what are the products giving/achieving for society". It was proposed that there could be a requirement that if a use is derogated then the use/product in question should be specifically named. They suggested that any changes to the CPR via the addition of an essential use concept could affect some demographics more than others.

Flexibility in criteria and feasibility/usefulness of a fall-back mechanism for emergency situations

- One trade association noted that for cosmetics it is the safeguard clause that applies, not the emergency clause. They pointed out that this clause allows Member States to unilaterally take action against a product where there is cause for concern. However, they did not see the essential use concept changing this clause much. They highlighted that emergency flexible approval could be beneficial for public health using the essential use concept.
- There was a discussion on preservatives and UV filters, since there are both hazards and beneficial effects associated with their uses. Flexibility in criteria was supported but to a greater or lesser extent. One NGO supported a more cautious approach and stated that it is important to take note of how often and in what these substances (preservatives and UV filters) are being applied in. However, one trade association pointed out that in some instances where specific use of these substances is very useful, appeared to support the concept of flexibility.

Coherence with other EU legislation

- One trade association noted that that the Biocidal Products Regulation is linked to both REACH and the CPR (e.g. in the case of preservatives) so ensuring coherence between these regulations will be important.
- One Member State authority indicated the need for coherence between cosmetics legislation and toys legislation as uses of substances can fall within the scope of both.
- Another trade association stated that there is potential incoherence between the annexes of REACH and the CPR.

3.8.4 Toys Safety Directive

Benefits from essential use concept in this legislation

- It was stated that toys do not necessarily need the highest quality of material and as such it might be easier to substitute certain chemicals. However, it was noted by an industry representative that some materials are chosen specifically for their application and a different material might bring certain negative impacts (e.g., plastic building bricks are made out of a special polymer and substituting it, for example, with wood might cause other health and safety issues such as splinters).
- An industry representative stated that the use of most chemicals in toys is not essential (e.g., UV stabiliser in toys) and that the current toys directive already contains a ban on all CMR substances (and a criteria for derogations from this ban). There is currently only one derogation of this ban, which indicates that the use of CMR substances in toys are not essential. An NGO stakeholder agreed with this point.

Feasibility

- It was said, that as the toys directive already bans CMR substances by default and contains a derogation system, the implementation of the essential use concept could be fairly straightforward. However, an industry representative stated that the current derogation system already has very strict requirements and as such there is no need to replace it.
- It was stated by an industry representative that the toys industry has much data on the exposure of certain chemicals to children and that the current version of the toys directive focuses on the safety in terms of exposure to a chemical. This is the case in the Nickel derogation, as the use has been deemed safe for the user. Other CMR substances might be present from the production process in very minimal concentrations, however the exposure from such cases has oftentimes been determined to be low risk. Such aspects would not be considered with an essential use concept, are however important when looking at the use of a substance.
- An industry representative stated that the Appendix A (of the Directive) requirements should be amended to implement a horizontal essential use concept.
- A Member State authority stated that the essential use concept should be consistent across legislation. For example, if a UV stabiliser is assessed for the usage in toys, it should also be assessed in all its other uses.
- It was also stated that cultural aspects should also be considered when regarding uses of the most harmful substances in toys.
- An industry representative said that toys are also regulated under other legislation and considering derogations for restrictions for one substance might cause the toy in question to not comply with other toys relevant legislation anymore. This should be taken into account when assessing the essentiality.

Flexibility in criteria and feasibility/usefulness of a fall-back mechanism for emergency situations

- No comments were made regarding this point, however emergency situations in the toys industry are not expected.

Coherence with other EU legislation

- The current version of the toys directive already mentions REACH and the CLP regulation and aims to be coherent with other chemicals legislation. An essential use concept would not necessarily strengthen the coherence. An industry representative stated, that if a substance is banned for consumer use under REACH, then it should also not be used in toys. It is crucial that there is a clear linkage between toys and other legislation. For example, the derogation process for chemicals in the toys and cosmetics regulation are quite similar. A different example is, that the use of the same substance might have different outcomes when assessed by different committees. Titanium dioxide was assessed by EFSA and SCHEER for food additives and toys with two different outcomes. Such aspects should be considered when implementing an essential use concept.

3.8.5 Food contact materials regulations

Benefits from essential use concept in this legislation

- There was no consensus amongst the stakeholders if an essential use concept should be applied in FCM regulations.
- According to an NGO the essential use concept could improve the management of the use of harmful substances in FCM.
- An industry association argued that in the current legislation there is a problem of 'retrospective application'. For example, lots of uses of substances which are allowed today, may not be in the future.
- Another industry association stated that there are already existing systems in place to consider derogations for the restriction of substances of concerns in FCM (authorisation process within REACH can also work for FCM). According to this stakeholder there is no need for an essential use concept in FCM legislations.

Feasibility

- One Member State authority noted that an essential use concept cannot be implemented in the positive list approach currently used in FCM regulations. The stakeholder argued that the positive list approach works well and there is no need for an essential use concept for FCM and suggested to expand the existing legislation regarding environmental aspects instead.

Flexibility in criteria and feasibility/usefulness of a fall-back mechanism for emergency situations

- No comments were made regarding this point.

Coherence with other EU legislation

- Stakeholders overall agreed that the essential use concept should be a horizontal concept.
- An authority representative argued that it has to be decided how to achieve coherence with different EU legislations. The stakeholder pointed out that only implementation should be adjusted for specific legislation needs.
- An industry association added that some aspects can be tackled in a horizontal approach but specific considerations for FCM need to be determined by e.g. DG SANTE or EFSA.

Additional comments

- One NGO stated that a merit in rethinking should be considered for FCM legislation. Currently there is a positive list for plastics in FCM, but not for paper. The example of PFAS in FCM in single used packaging items was mentioned which can lead to adverse

environmental/ health impacts. It is noted that this is considered in the ongoing application for PFAS restriction under REACH .

- One NGO stated that food packaging in general is not essential, and it is important to differentiate between essentiality of specific groups of additives within FCMs (e.g. colorants).

4. Next steps

4.1 Current gaps in knowledge and methodology to strengthen future work

As detailed in Sections 2 and 3, the inputs from stakeholders and the discussions during the workshop have provided the project team with important points to consider and follow up on when refining the essential use criteria and policy options, and when conducting the subsequent impact assessment.

The workshop has been helpful in identifying where a number of key knowledge gaps exist, which will help the project team to inform the next steps of the project. Key information needs are summarised in the table below:

Table 4.1 Key information needs

Aspect	Information needs
Fundamentals and definitions	• It has been highlighted from the discussions during the workshop that there are still areas of uncertainty or misunderstanding among stakeholders regarding some definitions of key aspects related to essential use (e.g. the definition of 'most harmful chemicals' and what the concept is actually applied to in terms of use).
Essential use criteria	• There is a need to ensure that the criteria used for the essential use concept (both the criticality/necessity and alternatives aspects) are underpinned by available data or by information requirements with the burden of proof on the entity that is requesting/proposing a derogation/authorisation. • The discussions during the workshop have identified a wider considerations for potential criteria/elements, for example aspects of circular economy and sustainability. It will need to be defined what information requirements are required for those that would be requesting derogations/authorisations and to be established if data available to operators is sufficient to be able to use this as a realistic criterion. • Several options or suggestions for how to potentially improve the process for the assessment of alternatives were made during the workshop, including opening up wider consultation or tendering of suppliers of alternatives. It will need to be further investigated if this can be a feasible approach in practice.
Essential use policy options	• It is noted from the discussion of coherence in EU legislation that there needs to be a more detailed understanding developed on how REACH and other pieces of EU legislation interact to identify exactly how the essential use concept would need to be adapted in its operation to apply to EU chemicals legislation, so this is effective and efficient. • Stakeholders have emphasised the importance of clarifying the interlinkages between the essential use concept and processes under REACH (e.g. those

subject to revision) like how the generic approach to risk management (GRA) will work in practice when the essential use concept is operationalised.

- No clear consensus was reached on whether the screening steps are considered useful or feasible in terms of making the process more efficient or effective. For example the practical issues around carrying out 'rapid' screening of alternatives were raised by stakeholders. Advantages and disadvantages of the screening steps were discussed, and will inform a more in-depth assessment of this process.

4.2 Action Plan for the project

The discussion points covered, and feedback gathered during this workshop (and the further information provided by stakeholders following the workshop) will feed into the next steps of the project. This will involve the following:

- **Refining the essential use criteria and policy options and drafting case studies**
  - Further refining criteria, based on feedback from the Commission, from the workshop and the targeted consultation.
  - Further refining options, based on feedback from the Commission, from the workshop and the targeted consultation.
  - Carrying out an in-depth analysis of options (including viability screening) as well as provide visuals for the agreed options, to illustrate the underlying processes.
  - Prepare the 8 case studies.
- **Carrying out the impact assessment**
  - Once the criteria and options have been finalised, we will carry out the assessment of impacts of those options (see Section 3.5).
- **Further stakeholder consultation**
  - Additional consultation activities are underway in the form of the open public consultation for the revision of REACH which includes a few high-level questions on essential use concept (and which is live until 15 April), the open public consultation for the revision of the Toys Safety Directive (open until 25 May) and the open public consultation for the revision of the Cosmetic Products Regulation (open until 20 June).
  - Additional consultation on the review of legislation on the restriction of the use of hazardous substances in electronics has been launched in the form of an open public consultation. This is open until 2 June.
  - Next steps in the targeted consultation include the development of a short survey. It should be noted that the survey will be made available to all organisations that registered for the workshop (limited to one survey response per organisation.

Follow-up interviews will be conducted with 20-30 organisations following the survey.

- We will be in touch directly with stakeholders in due course, and have noted those that expressed interest in being contacted, both during and after the workshop.

4.3 How to contact the project team

Please email any written comments or questions, and any information that will inform this project to the Wood project team at: essential.use.concept@woodplc.com.

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 • Criteria for essential use concept • 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 • Policy options for essential use concept in chemicals legislation (REACH and other legislation) • 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
Workshop Slides


Morning session slides.pdf


Afternoon session slides.pdf