‘Targeted’ stakeholder consultation - Study supporting the Commission in developing an essential use concept in chemicals legislation

This questionnaire

Wood E&IS GmbH (‘Wood’), in collaboration with Ramboll and additional scientific advisors, has been contracted by the European Commission to assist in the development and operationalisation of an ‘essential use concept’ to be applied horizontally in EU chemicals legislation. The terms of reference for this study can be found here. The work carried out under this contract is intended to feed into the following areas of ongoing work:

- Commission document on the horizontal criteria and application of the concept of essential use across chemicals legislation;
- The targeted revision of REACH;
- Revision processes of other pieces of chemicals legislation (such as the Food Contact Materials Regulations, Directive on the Restrictions of the use of certain Hazardous Substances in electrical and electronic equipment, End-of-Life Vehicles Directive, etc.), as relevant.

This questionnaire aims to support this study through consultation with expert stakeholders who can provide pertinent information and professional judgement or opinion on the practical application of introducing the essential use concept into REACH and other chemicals legislation, and of different options for doing so.

Please note that this questionnaire runs alongside the Commission’s ‘Public Consultation’ on the targeted revision of REACH and aims to collect more detailed information and insights than will be provided through that wider consultation.

The questionnaire is part of a number of consultation activities to support the project, including a workshop (held on 3 March 2022) and interviews with stakeholders.

This questionnaire is split into five sections:

- Section 1: General questions on your organisation
- Section 2: Questions on the horizontal concept of essential use
- Section 3: Questions on the essential use concept under REACH
Background to the essential use concept

The Chemicals Strategy for Sustainability - Towards a Toxic-Free Environment 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".

The concept would contribute to reductions in the use, and consequently the emissions, risks and impacts associated with the most harmful chemicals. The concept has the potential to protect the environment and human health from the most harmful chemicals by facilitating their phase out in non-essential uses and thereby preventing potential human and environmental exposure.

The ongoing work for the review and the revision of REACH and of some other pieces of chemicals legislation (see above) presents an opportunity to improve existing chemical regulatory processes. Improving processes to phase out the use of the most harmful chemicals is imperative given the current challenges in chemical regulation, for example, complex and slow restriction processes and highly burdensome authorisation procedures under REACH. These limitations can delay decisions and actions to adopt appropriate risk management measures for the most harmful chemicals, and therefore can result in their release to the environment as well as exposure of consumers and workers. An essential use concept could, in principle, help address these limitations by introducing more simplicity, transparency, predictability, and efficiency to prevent uses that are not necessary or critical (in terms of human health and/or the functioning of society), or where alternatives exist. Furthermore, it could provide more regulatory certainty to businesses.

The development and application of an essential use concept is also intended to encourage innovation in safe and sustainable chemicals to be used as alternatives to the most harmful chemicals. Lastly, setting clear and robust criteria would allow justification of decisions on discontinuing or continuing uses of these substances.

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. 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 what the costs would be. The understanding of these impacts will be developed following the Commission’s Better Regulation Guidelines, and will ultimately feed into the Impact Assessment for the targeted revision of REACH and potentially other legislation.

*Most harmful chemicals 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.
Completing the questionnaire

The questionnaire includes requests for information, data and opinions on the possible implications of introducing the essential use concept into REACH and other selected pieces of legislation.

The intended audience is a range of stakeholders, including regulatory authorities, industry, organisations representing civil society, and others.

If you do not have completely accurate information, please provide your best estimate.

If you are unable to answer any given question, please just move on to the next question.

We will not include details of you or your organisation’s name or responses in the presentation or analysis of information, without your explicit authorisation.

Statement on handling of confidential data for targeted consultation

It is recognised that some stakeholders may wish to provide confidential data as part of this consultation exercise. We have set out below the measures that we will take in order to protect any confidential information provided to the project team in connection with this work.

In particular, while information that stakeholders provide will be taken into account in our analysis, which will form the basis of our reporting to the European Commission, the measures that we will take to protect the data that stakeholders provide include:

- Ensuring that the confidential information provided will not be passed on to third parties outside the project team, directly or indirectly, partially or completely.
- Ensuring that the confidential information will only be made available to those project team members that need to know about it for the purposes of the project.
- Whilst the information provided is likely to be taken into account in the outputs (reports) from the contract, the confidentiality of the data will be preserved by:
  - Making anonymous all information relevant to specific companies, chemical substances and/or facilities within our reporting.
  - Not using the information provided for any purpose other than for this project.
  - Presenting uncertainty ranges in reported data (e.g. on quantities, emissions or costs) in order to avoid disclosing market-sensitive information.
  - Presenting aggregated data covering estimates for all companies and/or company average data, rather than data specific to individual companies.
  - Excluding other confidential information that stakeholders specify should not be included in the reporting.
If you require any further information or would like to discuss specific issues of confidentiality then please contact the project team. Please note, however, that we will not be able to enter into bilateral confidentiality / non-disclosure agreements with individual stakeholders.

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**About you**

* Your name
  
  Julie Schneider

* Organisation name
  
  CHEM Trust

Email address

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Telephone number

  +447564154378

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**Section 1: About your organisation**

1. Please indicate what type of organisation you represent:
   - [ ] Academic/ public research institution
   - [ ] Business association
   - [ ] Company/business
   - [ ] Consumer organisation
   - [ ] Consumer
   - [ ] Non-governmental organisation (NGO)
   - [ ] Public authority, Committee or another public organisation
   - [ ] Trade union
   - [ ] Other (please specify)

2. Please indicate the country of origin of your organisation:

   - [ ] Non-EU country

3. For **companies and industry associations**, please indicate if you are or represent:
   - [ ] Manufacturer of chemicals
   - [ ] Importer of chemicals
   - [ ]
Manufacturer of mixtures

- Importer of mixtures
- Manufacturer of articles
- Importer of articles
- Downstream user or distributor of chemicals
- Other (please specify)

4. For **companies and industry associations**, please indicate the sector(s) that your company/association operates in:

- A - Agriculture, forestry and fishing
- B - Mining and quarrying
- C - Manufacturing
- D - Electricity, gas, steam and air conditioning supply
- E - Water supply; sewerage, waste management and remediation activities
- F - Construction
- G - Wholesale and retail trade, repair of motor vehicles and motorcycles
- H - Transportation and storage
- I - Accommodation and food service activities
- J - Information and communication
- K - Financial and insurance activities
- L - Real estate activities
- M - Professional, scientific an technical activities
- N - Administrative and support service activities
- O - Public administration and defence; compulsory social security
- P - Education
- Q - Human health and social work activities
- R - Arts, entertainment and recreation
- S - Other service activities
- T - Activities of households as employers; undifferentiated goods- and services- producing activities of households for own use
- U - Activities of extraterritorial organisations and bodies

5. For **companies**, what is the size of your business?

- 0 to 9 employees
- 10 to 49 employees
- 50 to 249 employees
- More than 250 employees

6. Have you been involved in the following activities under REACH?

- Applying for an authorisation for a use of a chemical substance
- Arguing for a derogation from a restriction of a chemical
- Another activity related to authorisation (please specify)
- Another activity related to restriction (please specify)
- None of the above
Section 2: General questions on the horizontal concept of essential use

Reminder of the horizontal essential use concept

The assessment of essentiality would be undertaken in order to grant authorisations or justify exemptions /derogations from restrictions for the use of substances considered to be the most harmful chemicals, for which phasing out is a priority. The most harmful chemicals are defined in the Chemicals Strategy for Sustainability as chemicals that cause cancers, gene mutations, affect the reproductive or the endocrine system, or are persistent and bioaccumulative; chemicals affecting the immune, neurological or respiratory systems and chemicals toxic to a specific organ*.

The essential use concept would apply to substances that could be used on their own, in a mixture, an article, a product, a process or a service.

**Essentiality** for uses of “the most harmful chemicals” (not all chemicals!) =
- **Necessary** for health and/or safety **OR** **critical** for the functioning of society
- **AND** there are **no alternatives** that are **acceptable** from the standpoint of health and the environment

* PMT and vPvM substances are not mentioned in the CSS among the most harmful chemicals. However, the CSS announces that they will be a new hazard category under the CLP Regulation and included among the hazard classes for which substances of very high concern (SVHC) may be identified.

The Commission’s expectation is that ‘essentiality’ should apply to the use* of the most harmful chemicals and the technical function that they provide to that end use of the mixture, article, product, process or service, not in terms of whether a given article, product or service is essential. This relates to the technical function provided by the substance in the specified use and whether that use of the (most harmful) substance is essential to society (as described above). The technical function describes the role that the substance fulfils when it is used, i.e. what it actually does as such in a process or what it actually does in a mixture or article.

* The REACH definition of use is given in Article 3, point 24: use: any processing, formulation, consumption, storage, keeping, treatment, filling into containers, transfer from one container to another, mixing, production of an article or any other utilisation.

7. Do you agree that the essentiality of the use of the most harmful chemical in a product/article/mixture should be assessed, not whether a product/article/mixture/process/service is in itself essential or not?

- Yes
- No
- I don’t know

Please elaborate why/why not:
It will be very difficult to truly separate the essentiality of the use of a chemical in a product/article/mixture from the essentiality of the end product or application. We are of the opinion that both should be taken into consideration when doing the essential use assessment.

8. A particular use of a given substance may be essential in one product or sector but not in another. Therefore, a starting assumption is that the assessment of whether a use of one of the most harmful chemicals is essential should not be based on lists of products or sectors.

Do you agree with this statement?

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
<th>I don't know</th>
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<tr>
<td>... concerning products</td>
<td>[ ]</td>
<td>[ ]</td>
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<tr>
<td>... concerning sectors</td>
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Please elaborate why/why not:

The question is confusing. The second sentence seems to contradict the first one where it states that the use of a chemical might be essential is specific products and or sectors. We are of the opinion that it would facilitate the process to list specific products and sectors where essential uses might be expected. It could be an indicative/non-exhaustive list. It would bring clarity.

9. It is being considered whether the essential use approach should be used to justify authorisations of uses of the most harmful chemicals, or exemptions/derogations from restrictions. However, the conclusion on whether a given use is essential may change over time.

Do you agree that uses of substances considered as essential for society should be subject to reviews (i.e. any exemptions/authorisations should be limited in time)?

[ ] Yes
[ ] No
[ ] I don't know

Please elaborate why/why not:

Exemptions/derogations should have a sunset date for review of the conditions for the essential use based exemption/derogation. If the conditions are no longer fulfilled, then exemption/derogation must be revoked.

10. What are the key factors required to assess if the use of one of the most harmful chemicals is necessary for health and/or safety?

The aim is to eliminate the use of the most harmful substances to protect people and the environment. Therefore, the criteria must be stringent to limit derogations to the smallest number of uses possible (e.g. saving lives). The words “health” and “safety” can potentially be interpreted too broadly, for instance wellbeing could be part of “health”. Therefore, these terms must be strictly defined in the context of the essential use concept. The definition must be narrow and stringent.
11. What are the key factors required to assess if the use of one of the most harmful chemicals is **critical for the functioning of society**?

As above, the definition/interpretation of “critical for the functioning of society” should be as narrow as possible to limit derogations for the most harmful chemicals to a small number of uses. Listing examples of sectors might be helpful to clarify the context.

12. Should **cultural and heritage aspects** be considered in the assessment on whether the use of one of the most harmful substances is **critical for the functioning of society**? If so, how?

- ☐ Yes
- ☐ No
- ☐ I don’t know

If so, how:

13. What are the key factors required for the **assessment of acceptability of alternatives** from the standpoint of the environment and health?

In our opinion this should be based on the intrinsic hazardous properties

14. Under the current REACH authorisation process, third parties can provide information on alternatives in response to individual authorisation applications for specific uses. Likewise, for REACH restrictions, a public consultation on proposed restrictions is undertaken, which can cover information on alternatives.

Should any actor (**other than industry**) provide information and evidence on alternatives?

- ☐ Yes
- ☐ No
- ☐ I don’t know

Please elaborate which actors should be incentivised to provide information on alternatives:

- Alternative providers, academic experts, other experts

15. What are the key lessons learnt from analysis of alternatives under REACH and other legislation that could be considered for this step (identifying whether there are acceptable alternatives from the point of view of environment and health) in the essential use concept?

Companies can submit information regarding the availability of alternatives, however an independent expert body should also be involved to support/deepen the assessment. In addition, the conclusion on the non-availability of acceptable alternatives cannot come from the company applying, it should be taken by an independent expert body.
Section 3: Questions on the essential use concept under REACH

Necessary for health/safety

16. Under REACH, what information should be provided to demonstrate that a use is necessary for health or safety?

Precise description of the function of the chemical in the product/mixture/application and precise description of the end use under consideration. Both the function and the end use should be considered to assess whether this particular use of a chemical would fall under the scope of “necessary for health or safety”.

17. Under REACH, who should bear the burden of proof in demonstrating that the use of one of the most harmful chemicals is necessary for health or safety?

- Industry (if you select this, please elaborate in the open text box which part of the supply chain should bear the burden of proof)
- Member States Competent Authorities
- ECHA
- Other (please specify)

Industry (please elaborate which part of the supply chain should bear the burden of proof):

The burden of proof should be on the company making the claim, which can be any part of the supply chain.

Please elaborate why:

The burden of proof should be on the company making the claim, which can be any part of the supply chain.

18. Under REACH, who should assess the information to confirm whether a use of one of the most harmful chemicals is necessary for health or safety?

- ECHA Secretariat
- One of the ECHA scientific Committees (SEAC/RAC)
- The Member State Committee of ECHA
- European Commission, in consultation with the REACH Committee
- A new body/committee
- Other (please specify)

Other (please specify):

Existing committees in their current form would lack some of the expertise necessary to make the assessment. Either additional capacity and expertise could be added to one of the existing committee or a new body/committee could be created and dedicated to this task. In any case, new expertise in the fields of health and safety, ethics and sociology for instance should be considered.

Please elaborate why:
Existing committees in their current form would lack some of the expertise necessary to make the assessment. Either additional capacity and expertise could be added to one of the existing committee or a new body/committee could be created and dedicated to this task. In any case, new expertise in the fields of health and safety, ethics and sociology for instance should be considered.

19. What do you expect to be the key challenges or obstacles to assessing the necessity for health and safety if the essential use concept is implemented under REACH?

Subjectivity around the interpretation of necessity for health/safety. Which is why these terms must be strictly defined.

Critical for the functioning of society

20. Under REACH, what information should be provided to demonstrate that a use is critical for the functioning of society?

Precise description of the function of the chemical in the product/mixture/application and precise description of the end use under consideration. Both the function and the end use should be considered to assess whether this particular use of a chemical would fall under the scope of “critical for the functioning of society”.

21. Under REACH, who should bear the burden of proof in demonstrating that the use of one of the most harmful chemicals is critical for the functioning of society?

- Industry (if you select this, please elaborate in the open text box which part of the supply chain should bear the burden of proof)
- Member States Competent Authorities
- ECHA
- Other (please specify)

Industry (please elaborate which part of the supply chain should bear the burden of proof):

The burden of proof should be on the company making the claim, which can be any part of the supply chain.

Please elaborate why:

The burden of proof should be on the company making the claim, which can be any part of the supply chain.

22. Under REACH, who should assess the information to confirm whether a use is critical for the functioning of society?

- ECHA Secretariat
- One of the ECHA scientific Committees (SEAC/RAC)
- The Member State Committee of ECHA
- European Commission, in consultation with the REACH Committee
- A new body/committee
- Other (please specify)

Other (please specify):
23. What do you expect to be key challenges or obstacles to assessing criticality for functioning of society?

Subjectivity around the interpretation of criticality for the functioning of society. Which is why this must be strictly defined.

**Availability of alternatives when implementing the essential use concept in REACH**

24. If the essential use concept is implemented under REACH, what information should be provided to demonstrate that there are no available alternatives for a use of one of the most harmful chemicals?

Should provide a full assessment of alternatives stipulating what has been investigated (type of alternatives including chemical substitution and product/technic substitution) and the sources used for the investigation. In addition, a substitution plan should be provided, to demonstrate effort is going into researching and/or developing alternatives.

25. Under REACH, who should bear the burden of proof in demonstrating that there are no available alternatives for a use of a substance acceptable from the standpoint of environment and health?

- Industry (if you select this, please elaborate in the open text box which part of the supply chain should bear the burden of proof)
- Member States Competent Authorities
- ECHA
- Other (please specify)

Industry (please elaborate which part of the supply chain should bear the burden of proof):

The burden of proof should be on the company making the claim, which can be any part of the supply chain.

Please elaborate why:

The burden of proof should be on the company making the claim, which can be any part of the supply chain.

26. Under REACH, who should **assess** the information to confirm that there are no alternatives for a use of a substance that are acceptable from the standpoint of the environment and health?

- ECHA Secretariat
- One of the ECHA scientific Committees (SEAC/RAC)
- The Member State Committee of ECHA
- European Commission, in consultation with the REACH Committee
- A new body/committee
- Other (please specify)
Please elaborate why:

Regarding the assessment of the alternatives, in the end, it is about proving the absence of acceptable alternatives to grant a derogation for essential use. The industry could submit evidence but should not be the one proving that there are no acceptable alternatives.

A new body/committee should be created and dedicated fully to the assessment of alternatives. Input from external independent experts is lacking in current assessments but is critical to this process. Such a body could also be a hub to support companies in performing alternative assessment.

Current experience under REACH has shown that alternative assessments need improvement (see ChemSec report from 2018 - How to find and analyse alternatives in the Authorisation Process https://chemsec.org/publication/authorisation-process,reach/how-to-find-and-analyse-alternatives-in-the-authorisation-process/). The creation of an independent body dedicated to alternative assessment would be beneficial.

27. Do you agree with the following statements:

<table>
<thead>
<tr>
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<th>Yes</th>
<th>No</th>
<th>I don't know</th>
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<tbody>
<tr>
<td>The current <strong>ECHA guidance for analysis of alternatives</strong> should be applicable to assess the availability of alternatives under the essential use concept.</td>
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<tr>
<td>Acceptable alternatives should be those that can allow the product/service/article to achieve a <strong>sufficient level of performance</strong> (but not necessarily more) in terms of health/safety or attributes that are critical for the functioning of society.</td>
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<tr>
<td>The assessment of alternatives should cover all lifecycle stages.</td>
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<tr>
<td>Information provided for the analysis of alternatives should include information on the <strong>risks to human health and the environment</strong> related to the manufacture and use of the alternatives.</td>
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<tr>
<td>Information provided for the analysis of alternatives should include information on the <strong>availability</strong> of the analysed alternatives, including the time scale.</td>
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<tr>
<td>Information provided for the analysis of alternatives should include information on the <strong>technical feasibility</strong> of an alternative <strong>for the company applying for an authorisation / derogation from restriction.</strong></td>
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<tr>
<td>Information provided for the analysis of alternatives should include information on the technical feasibility of using an alternative <strong>within EU society as a whole</strong>, not simply from the perspective of one specific applicant.</td>
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<tr>
<td>Information provided for the analysis of alternatives should include information on the economic feasibility of an alternative <strong>for the company applying for an authorisation / derogation from restriction.</strong></td>
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</table>
Information provided for the analysis of alternatives should include information on the economic feasibility of using an alternative within EU society as a whole, not simply from the perspective of one specific applicant.

Please elaborate on any of the above answers, if you wish:

One key aspect when assessing alternatives is to avoid regrettable substitutions (from a toxicological and environmental point of view). However, it is very important to keep the balance right, the alternatives should not go through more scrutiny than the substances being controlled, as this just creates delay and further emissions.

It is also important to acknowledge that a change and/or lowering of the product performance/convenience, as a consequence of using alternative substances and/or technologies, may be unavoidable and acceptable as long as it does not jeopardise the availability of essential services to the health, safety and functioning of society. See as a case study Judgment of the General Court, 7 March 2019, REACH — Commission Decision authorising the use of lead sulfochromate yellow and of lead chromate molybdate sulfate red — Article 60(4) and (5) of Regulation (EC) No 1907/2006 — Examination of the lack of availability of alternatives — Error of law. https://curia.europa.eu/juris/document/document.jsf?text=&docid=211428&pageIndex=0&doclang=EN&mode=req&dir=&occ=first&part=1 It is explicitly stated that some reduction in performance in acceptable (Point 90).

Similarly, it is important to accept that the cost might be initially higher when moving to alternative substances/technologies.

28. What do you expect to be the key challenges or obstacles to assessing the alternatives in the context of applying the essential use concept in REACH?

- Limited access to information regarding availability of alternatives.
- Different views regarding acceptable level of performance for the alternatives.
- The point of view of the applying company will be biased, independent experts will be needed to challenge the company assessment.

29. Is there any element or step not currently covered by ECHA’s guidance on the assessment of alternatives (see guidance on the preparation of an Annex XV dossier for restrictions and guidance on the preparation of an application for authorisation) that should be included in the essential use concept?

- Yes
- No
- I don’t know

30. Is there any element or step that is currently covered by ECHA’s guidance on the assessment of alternatives (see guidance on the preparation of an Annex XV dossier for restrictions and guidance on the preparation of an application for authorisation) that should not be included in the essential use concept?

- Yes
- No
- I don’t know

Negative (e.g. costs) and positive impacts (e.g. benefits) of implementing an essential use concept in REACH
31. What would be the main negative impacts (including costs, administrative burden, etc) of introducing the essential use concept in deciding on authorisations and/or exemptions from restriction under REACH?

A risk would be to slow down the process, making it more burdensome and less efficient. For instance, listing all possible uses of a chemical if concern and assessing them all one-by-one for essential use would make the process extremely burdensome for the regulators and therefore inefficient. It is very important that the introduction of the essential use concept speed up regulation and facilitate the phase out of the most harmful substances, by simplifying existing processes, not the opposite.

32. Do you have any suggestions on how those negative impacts, including costs could be reduced?

Only a narrow range of uses should be assessed for essential use. The default position should be that all the uses of the substances in scope (the most harmful chemicals) will be prohibited, and the industry comes forward to apply for essential use exemptions (via a call for evidence for instance). The essential use assessment is then performed only on the uses the industry has come forward with. There is still a risk of receiving a large number of essential uses claims, including duplicates. It will be necessary to find a way to streamline the process by grouping claims.

In addition, the essential use assessment must start with the assessment of necessity/criticality. The assessment of alternatives should be done only for uses deemed necessary/critical.

Regarding costs: application for exemption based on essential use criteria could be subjected to a fee. This could be a way to raise funds to fund the new bodies, additional expertise needed for the assessment.

33. What would be the main benefits of introducing the essential use concept in deciding on authorisations and/or exemptions from restrictions under REACH?

It would fill a gap by preventing derogations/exemptions for unnecessary uses. This would bring benefits in terms of protection of human health and the environment by leading to a significant percentage reduction of the presence of the most harmful substances in products.

It would also bring clarity to the industry regarding the necessary phase out of the most harmful substances and boost safe and sustainable innovation. More companies would step forward to develop safer alternatives for necessary/critical uses, this would trigger innovation.

34. Do you have suggestions on how to maximise those benefits?

The essential use criteria must only recognise a narrow range of uses as essential: this involves on hand stringent definitions around necessity and criticality, and on the other hand broad definitions around alternatives.

In addition, echoing the Montreal Protocol, the default position should be: The use of the most harmful chemicals is a priori not acceptable.

Potential screening steps

The implementation of an essential use concept under REACH, for the most harmful chemicals, would require an assessment of the necessity for health/safety, the criticality for the functioning of society and the availability of alternatives. Such assessments can be time-consuming and resource intensive.
Initial screening steps under REACH could be implemented ahead of more in-depth assessments, to quickly filter out clearly non-essential uses, or to prioritise uses likely to be considered essential, with a view to shortening the decision-making process.

35. Do you agree with the following statements?

<table>
<thead>
<tr>
<th>Statement</th>
<th>Yes</th>
<th>No</th>
<th>I don't know</th>
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<tbody>
<tr>
<td>An initial screening for alternative products available on the market, but without the most harmful chemical would simplify and speed up decision-making. For example, if substance X is used in a shampoo, this initial step would screen products available on the market to see whether other shampoos are available without substance X.</td>
<td></td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>An initial screening for necessity/criticality would simplify and speed up decision-making.</td>
<td></td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Both screenings for alternative products available on the market and for necessity/criticality would simplify and speed up decision-making.</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Screening steps would not simplify and speed up decision-making.</td>
<td>X</td>
<td>X</td>
<td>X</td>
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</table>

Please elaborate:

If you have selected ‘both screenings’, do you think the two screenings (on criticality/necessity and on alternatives) should be done simultaneously or should they be done one after the other?

- Simultaneously
- One after the other
- I don’t know

36. Do you think that such screening steps could provide an opportunity to adapt information requirements early on in the assessment of essentiality to allow for simplification and better targeting of a more detailed assessment (either of alternatives or of criticality for the functioning of society and necessity for health or safety), in particular for clearly critical uses?

- Yes
- No
- I don’t know

Please elaborate:

It would help shortlisting uses where more time and resources should be invested for an in-depth assessment.

37. If a simplified screening step were to be implemented for alternatives, what are the key considerations or information sources that should be taken into account in the screening?
A screening process would not be sufficient to conclude on the absence of alternatives – only on the availability of alternatives.

38. If a simplified screening step were to be implemented for criticality / necessity, what are the key considerations or information sources that should be taken into account in the screening?

A screening process would not be sufficient to conclude on criticality/necessity – only the non-criticality/non-necessity of a use.

39. What would be the main benefits of such screening steps?

Streamlining the assessment and speeding up the process

40. What would be the main challenges of such screening steps?

Potentially a lot of appeal to contest a decision of non-essential use. If too many, could lost all the time gained from screening.

Other questions

41. Do you see a need for an additional fall-back mechanism for emergency situations for uses of the most harmful chemicals (until they are assessed as essential or not essential under REACH following a more in-depth assessment)?

Please note the possibilities already offered by Articles 2(3) and Article 129 of REACH.

- Yes
- No
- I don't know

42. Can you think of other similar examples (other than emergency situations) where flexibility in the application of the essential use concept or process would be justified?

- Yes
- No
- I don't know

Please elaborate:

43. Do you envisage any overlap and/or inconsistency/incompatibility between applying the essential use concept and any other provision under REACH?

- Yes
- No
- I don't know

Please elaborate:
Section 4: Questions on the essential use concept under legislation other than REACH

44. Do you think there are pieces of legislation other than REACH that would benefit from an essential use concept? (for example 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)

- Yes
- No
- I don't know

Please elaborate which:

Food Contact Materials

45. Are there any features of such legislation that mean that the essential use concept should be implemented differently to how it might be implemented in REACH, i.e. if an essential use concept was introduced, should it be done differently than under REACH?

- Yes
- No
- I don't know

Please elaborate:

46. What would be the main benefits of introducing the essential use concept in determining exemptions from restrictions in such legislation? Please specify the legislation you are referring to.

The most harmful chemicals should be phased out, therefore they need to be eliminated wherever they are being used.

47. What would be the main negative impacts including costs of introducing the essential use concept in determining exemptions from restrictions in such legislation? Please specify the legislation you are referring to.

48. What would be the key practical challenges and/or any unforeseen negative consequences in implementing the essential concept in such legislation, in particular considering the existing provisions of the legislation as well as the types and characteristics of products regulated in this legislation?

The slow reform process of the FCM legislation.
49. Would the essential use criteria in the Chemicals Strategy for Sustainability (use to be necessary for health/safety and/or critical for the functioning of society and no acceptable alternatives from the standpoint of health and the environment) be compatible with the objectives and provisions of such legislation?

☐ Yes
☐ No
☐ I don’t know

Please elaborate:

The FCM legislation needs to be improved (see https://chemtrust.org/food-contact-materials/)

Section 5: Any other information

If you would like to provide any further information, please give details here, and if you would like to share any documents/attachments, please do so below.

5000 character(s) maximum

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/CHEM_Trust_comments_Essential_use_workshop_March_2022.pdf

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