Downstream Users of Chemicals Co-ordination group

DUCC Assessment of Alternatives – Workshop 2

DUCC acknowledges that Assessment of Alternatives (AoA) can be a difficult topic. We also believe that downstream users have sofar not been adequately involved in the current process, which in fact contributes to the difficulties authorities face when trying to obtain all the required information. We thus wish to engage on this issue, because, to avoid unintended impacts on EU Society, a robust Assessment of Alternatives is key to good decision making. To address the topic, DUCC wishes to engage with Member State representatives, Commission, ECHA, NGOs as well as experts from the DUCC network/ Industry through a series of workshops to address key complex questions and to offer solutions.

A kick-off workshop took place on the 9th of March. The aim of the first workshop was to start the exchange and have a constructive, technical discussion, focusing: on criteria and process and to address the importance of AoA as a key building block for the success of the REACH processes. DUCC understands that MS's have difficulties with AoA in the Authorisation and Restriction step and MS were thus asked to share their experience.

- Thought starter to the kick-off DUCC Assessment of Alternatives workshop: Link
- Summary of the DUCC Assessment of Alternatives workshop that took place on the 9th March: Link

Based on the input received in the first workshop DUCC proposes the following next steps:

- **Workshop 2: 24th of April:** Progress the discussion that began briefly at the workshop on the 9th of March on what would a technical body supporting the Assessment of Alternatives look like? Financing? Role of industry associations? Dealing with multiple substances and multiple uses?
- **Topics to be considered for next workshops:** i) Supplier – customer communication concerning alternatives. ii) Technical equivalence – how to define technical equivalence? Meant as technical sufficiency and considering what is an acceptable loss of performance?

In this document DUCC shares our proposal for the workshop in April. It is an idea of a technical body in ECHA that would support assessment of alternative discussions. This is a draft idea that we hope to develop further considering the input that will be shared in the DUCC workshop in April.

To express interest in the DUCC Workshop of DUCC work on Assessment of Alternatives please register here: https://survey.zohopublic.eu/zs/5PDHF2

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Elements of a Body Supporting Assessment of Alternatives (AoA)

Criteria to be evaluated:

1. Sufficient substance hazard data
2. Safety of alternatives
3. Technical equivalence
4. Sustainability impact
5. No unacceptable barrier to market

Main ECHA AoA Committee

Similar setting as MSC (ECHA chairs, MSs discuss and vote, COM & ASOs present, guests when relevant). Discuss (in closed and open sessions – CBI):

- Roadmap, setting priorities
- Call for sub-groups formation for each use of the substance to substitute
- Decision on sufficiency of hazard data for alternatives identified in sub-groups, AoA can proceed if ok
- Reports received from sub-groups

Report

Report

Report

Sub-group Use 1

ECHA Chairs, Industry experts for use 1, NGOs… compile information on:

- Specific risk assessments of alternatives
- Technical equivalence
- Comparison of impact on sustainability
- Market hindrance

Summarize findings in a transparent and structured way.

Propose timelines needed for innovation to new alternatives.

Sub-group Use 2

Sub-group Use 3

DUCC presents a System that is inspired by the 'Montreal Protocol Technical Committees' & 'Member State Committees in REACH', with some additional considerations from DUCC members.

Early analysis of alternatives: The assessment of alternatives is a key element to consider in any regulatory process aiming to ban chemicals or uses from the market. AoA should be assessed at an earlier stage of the process. It would significantly improve the knowledge of the current trends and the identification of the most suitable and effective regulatory action to consider with the aim of avoiding regrettable substitutions.

Workplan/ roadmap on substances and uses to be focused on: A roadmap of both substances and uses to be focused on is key, and unavoidable, considering that certain substances might have a high number of uses across a variety of sectors. For downstream user sectors a clear understanding of the uses in scope is crucial to identifying product categories in scope and to identify the expertise needed from a downstream user perspective to bring to the discussions.

A *Main ECHA Assessment of Alternatives Committee* would support the creation of a workplan/ roadmap on substances and uses to be targeted. It would include refined information providing precise identifiers for the targeted chemicals (Name, CAS #, EC #, etc.) and targeted uses (considering exposure).

Main ECHA Assessment of Alternatives Committee:

The main ECHA Assessment of Alternatives Committee would collect reports/ proposals, and recommendations from sub-groups on use and synthesize these for regulatory purposes. Propose substitution plans, considering ongoing innovations in new substances. If lack of alternatives is demonstrated – a substance can be used safely while alternatives are being explored. The ECHA Committee would act to coordinate the expertise coming from the sub-groups on use.

Sub-Groups on Use:

- Creation of 'Sub-Groups on Use'. These groups would, for uses in scope, assess alternatives in terms of: specific risk assessments of alternatives, technical equivalence, evaluation and comparison of the impact on sustainability, market hindrance, and proposed timelines needed for innovation to new alternatives
    - Information collected based on standardized criteria (examples data collection on page 4).
- Technical discussions would be led in these '*Sub-Groups on Use'* led by Member States and industry technical experts using the substance groups and then reported publicly in a transparent format.
- Civil society, other stakeholders e.g. not in kind alternative suppliers including academia should be included to provide feedback.

Data collection in Sub-groups on Use based on Standard criteria:

An upfront tabulation of technical requirements allows a better understanding of the reasons of why a substance is used, what are the no-go properties and why – to help streamline decision making.

Safety of the alternative	*Example answers*
Collection of all relevant hazard, (eco) toxicological information for (all) alternative(s) for the application in discussion	
Collection of all exposure data/scenario for the use in discussion	
Is the proposed alternative also safe for use for the application in question?	*Compilation of RCR values*
Technical equivalence	
Dependent on a specific use (see examples below)	
Sustainability impact	
For the targeted application and its alternative	
Market barriers	
Is the proposed alternative patented for the application in question?	*Yes/ No*
If patented, what is the remaining protection time	*In years*
How many suppliers are available?	*Number of suppliers – to avoid monopolies*
What is the share of EU production of the alternative substance?	*Percentage produced in the EU*
What are the main sources for the production outside EU?	*Countries of external supply*
How does the alternative compare cost-wise?	*To allow an economic impact analysis*

Technical equivalence requirements *(e.g. paint)*	*Example answers*
Coating durability	
Drying time	*3h instead of 1h*
Ease of application	

Technical equivalence requirements *(e.g. preservatives)*[1]	*Example answers*
Spectrum of activity	*Specific spectrum of activity – formulation, concentration needed*
pH activity	*pH spectrum of activity*
Shelf life of formulated product	*Years of shelf life*
Concentration	*% concentration*
Solubility/ compatibility	*Water or oil soluble*
Odour/ colour	*If preservative affects color or odor? Any ways to manage this?*
Compositional information	
Additional performance benefits	*Provides benefits to product beyond preservative, e.g.,antioxidant*
Demonstrated track record of efficacy	*Demonstrated safety and efficacy track record in another sector*
Mfg/processing/use	*Can withstand heating or formulating in cold process*

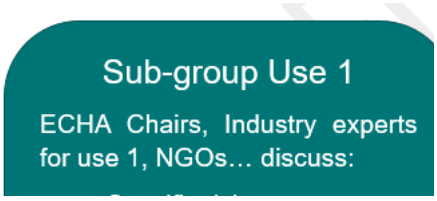
[1] https://greenchemistryandcommerce.org/documents/GC3PreservatvesCriteria1.pdf

Questions for discussion in DUCC April Workshop:

- **How to ensure that the system is transparent and neutral and as such credible (for all parties)?**

- **Setting a workplan for substances and uses**
    - How to set this workplan? Principles and priorities?

- **Leadership of the Sub-groups on Use:**



In the flowchart being proposed on page 3, DUCC members suggest for ECHA to chair the *Sub-groups on Use*. However, there are other leadership options for such a group. Chairmanship could also be given to:

- Member State competent authority
- Co-leadership between MSCA and industry sector targeted by said use
- Co-leadership between MSCA and more than one industry sector if use has overlap(s)
- Industry leadership only.
- Etc.

- **How to ensure a substance that is claimed as an alternative, is in fact a valid alternative?**

- **Funding of such a system?**

- **Better considering confidentiality of this system**?

- **Elements needed to allow business certainty in Europe?**

- **When to trigger the Assessment of Alternatives in the REACH process?**