Downstream Users of Chemicals Co-ordination group

Revision of EU Regulation No 1907/2006 on registration, evaluation, authorisation and restriction of chemicals (the REACH regulation)
DUCC input to consultation on Inception Impact Assessment

The Downstream Users of Chemicals Co-ordination group (DUCC) supports the objectives of the Chemicals Strategy for Sustainability (CSS) aiming at achieving a higher level of protection of citizens and the environment against hazardous chemicals and encouraging innovation for the development of safe and sustainable alternatives. However, DUCC notes that the removal of hazardous chemicals from the EU market simply based on hazard and not on risk could be very detrimental for the EU Society and be against some objectives of the Green Deal as could result in the use of more raw materials, energy, water, and higher greenhouse gas emissions.

DUCC urges the European Commission not to rush decision-making processes for REACH (or any other legislation) in order to meet unrealistic deadlines, set in the CSS, but to ensure that these are conducted properly in line with the principles of Better Regulation[1]. DUCC would like to spotlight that it is very important to assess the impacts of proposed changes to the hundreds of DUs (a lot of them being SMEs) operating in EU, as, due to foreseen changes, the monetary and administrative burden for DUs could increase significantly. Thus, considering the magnitude of the proposed changes and the level of ambition set in the CSS, DUCC would like to highlight the value of impact assessment and the need for the proper dialogue with all stakeholders at all stages of the process.

The Downstream Users of Chemicals Co-ordination group (DUCC) welcomes the opportunity to participate in public consultation (PCo) on Inception Impact Assessment for REACH and wishes to share the following comments on the European Commission Roadmap for the revisions of REACH:

- **Generic approach to risk management**
  - It is a very simplistic approach to a complex situation.
  - Regulating chemicals only on the basis of their hazard, is excessively simplistic and risks discriminating and removing from the market chemicals with high societal, environmental and economic benefits. Such removal could result in a lack of products on the market to address public health crises.
  - Chemicals should be regulated on the basis of sound science reflecting both hazard and exposure (i.e., safe use).
  - The 'generic risk management' approach (based on hazard) should be applied in a targeted way, to substances and/or uses where adequate control of risk has not been demonstrated.
- **Essential Uses**
  - DUCC recognises that discussions on this topic and any potential decisions on what will be recognised as an "essential use" will be of highly political nature with unavoidable socio-economic consequences.

[1] Commission Communication on Better Regulation published 29 April 2021

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- In our view a generic "definition based" approach to "essentiality" is not a solution that can ensure sufficient clarity and predictability to industry and consumers.
- The value chemical substances/ products could bring to the society should be also considered. In some cases, chemical/ product when looked at in isolation might not be considered "essential". However, from sustainability perspective it could bring value in ensuring durability of an article (lesser use of raw materials and energy consumption and thereby addressing the objectives of Circular Economy).
- "Essentiality" should not be considered as permanent as will go through constant change following societal needs and/or technical development (recent COVID-19 crisis is a good example of changes in societal needs).
- The lack of clarity on how this concept will be developed and implemented brings a lot of uncertainty to DUs sectors.

- **Combination effects of chemicals and mixture assessment factor (MAF)**
  - A generic MAF is a very simplistic approach to a complex situation.
  - DUCC is not in favour of introduction of one generic/fixed MAF to be applied to all chemicals. A blanket MAF would be arbitrary and not based on science, covering largely hypothetical exposures and risks rather than real-life scenarios and could possibly result in removal of non-hazardous products containing hazardous components at concentrations below classification or actual effect limits from the market.
  - Broadly applied a MAF will result in unnecessary compliance activities that will ultimately not achieve the regulatory goals. Thus, MAFs, when introduced, should be proportional, targeted, and built on a solid scientific knowledge base as well as should allow for specific evidence-based refinements.
  - MAF could only be relevant to unintentional mixtures and therefore should be only applied to the RCRs.
  - Safety factors are already intrinsically added when deriving an acceptable level, such as DNEL or PNEC and these are already conservative.
  - The default application of an additional safety factor such as a MAF would result in unrealistically high use of the precautionary principle.
  - On top of other existing assessment factors adding a MAF of 10 equals to 10 times more exposure which would overestimate the risks in most cases.
- **Simplifying communication in the supply chains** (including in particular harmonised electronic formats)
  - Communication on how chemicals can be used in a safe manner along the supply chain is key to secure proper risk control by downstream users. Thus, DUCC acknowledges the key role of formulators in the centre of the supply chain, since they need to ensure the safe use both of the substances/mixtures they receive and of the mixtures they place on the market.
  - DUCC reiterates its commitment to the improvement of supply chain communication and welcomes EU COM initiative to look for ways how to improve communication in the supply chain.
  - A uniform exchange standard (e.g., XML-based) for conveying relevant safety data electronically along the supply chain could be useful if simple/user friendly

interface solutions are developed as that would facilitate the use of electronic exchange in all the supply chain. However, we would like to point out that any decision on the strategy to ensure implementation of any new digital solutions in the market can only be taken on the basis of a favourable assessment of the benefits versus the costs (not purely financial).

- **One substance one assessment**
  - The concept could be appropriate if it is only applied to the hazard assessment as it could streamline the process and seemingly different outcomes due to hazard assessments carried out at different times by different bodies, under different legislations could be avoided.
  - We are of the opinion that the risk assessment is specific to uses and expertise should remain with existing agencies responsible.
- **Polymer registration**
  - We are of the opinion that only polymers that pose a concern should be subject to registration.
  - The data requirements, tonnage cut-offs, testing schemes should account for polymer specificities and should be understandable, implementable, and transparent.
  - The priority should be given to development of “fit for purpose” registration requirements that could fulfil REACH regulatory aims to ensure a high level of protection for human health and the environment.
  - Testing should be required only when hazards are unknown, cannot be reasonably anticipated based on polymer structure, and would affect the way the materials are handled in commerce. Testing should not be required for polymers that are already managed in such a way that anticipated risks are mitigated. Animal testing should be used as a last resort.
  - In order to avoid double registrations, for polymers that are subsequently registered, registration of the new constituent monomers should no longer be required and for already registered monomers, registrants should be permitted to abandon the corresponding monomer registrations, if the monomers are not placed as such on the market. In our view due to upcoming new requirements for PRR registration, current legal obligations laid out in REACH Article 6.2 & 6.3 will need to be modified or deleted.
  - Sufficient time should be given to industry to prepare for the polymer registration as was done during the registration of non-polymeric substances.
- **Enforcement**
  - Better cooperation between Enforcement authorities in different Member States is needed in order to establish harmonised interpretations and enforcement practices across EU.
  - Coordinated enforcement projects across Member States, in cooperation with industry, need to be continued.
  - Enforceability as well as proportionality of regulatory measures needs to be ensured before a regulatory proposal is adopted to ensure a level-playing field.
  - A more consistent and joined-up approach to enforcement controls, especially on e-commerce and imports, should be established. Efforts must be made to ensure

a level playing field between EU made products/articles with ones coming from outside EU.

- **Modifications to the authorisation and restriction processes**
  - A transparent procedure to ensure that the best and most efficient risk management option can be chosen should be establish. We would also like to stress the importance of appropriate and transparent consultation process for all interested stakeholders and third parties.
  - Managing chemicals based on a good understanding of their uses and of potential exposures should continue to be at the core of risk management. Science and data need to remain at the heart of decision-making. Banning of entire groups of substances (or substance uses) irrespective of the real risks and in some cases even without hazardous intrinsic properties should not become a routine activity.
  - DUCC understand that both authorisation and restriction processes are very complex and due to that deserve a detailed analysis. We are of the opinion that it would be damaging to reduce the complexity of the processes with simplistic solutions based on hazard.
  - In order to reduce burden to authorities, DUCC suggests to increase industry engagement by allowing industry to take on more burden in activities that currently in the hands of the Authorities to relieve them, but under their control (for example., to be in lead in preparing Risk management options analysis (RMOA)).
- **The evaluation of registration dossiers is complex**
  - DUCC would like to reiterate that Downstream Users could contribute to this process, as they may be in possession of information useful for substance evaluation, such as use and risk assessment data, sometimes measured data.
  - A registration dossier represents a comprehensive effort from an Industry Registrant to deliver information. The evaluation of such dossier is by nature complex and the EU can be proud to have the most comprehensive system in the world. This complexity requires resources and time and should not be taken as a problem as such. Proper scientific assessment should be always allowed. If the speed of evaluation should be increased, one could envisage to increase the resources allocated to such activity.

Overall, DUCC members are highly committed to successfully implement REACH which has been one of the most important regulations to ensure consumers and products safety in Europe on chemical risks. However, DUCC is of the opinion that any future actions to be taken should preferably involve using and strengthening existing tools as the set goals could be achieved by securing an overall better implementation of REACH regulation and harmonisation of requirements between all horizontal legislations related to chemicals management. In order to decrease burden to authorities and speed up the REACH processes industry could actively participate in developing Risk management options analysis/ identifying chemicals of concern with MS authorities/ ECHA. The full supply chains should be involved in an effort. It could be noted that Industry has the resources and expertise to provide help in defining various concepts and finding appropriate solutions. At last, actions to be taken should not only be targeted at EU

industry but also involve society as whole (better education) as might require to make changes to individual behaviour in day to day life.

Brussels, 31 May 2021

About DUCC

DUCC is a joint platform of **11 European associations** whose member companies use chemicals to **formulate mixtures** (as finished or intermediary products) for professional and industrial users, as well as for consumers.

DUCC focuses on the downstream users' needs, rights, duties and specificities under **REACH** and **CLP**.

DUCC's membership represents several important industry sectors, ranging from cosmetics and detergents to aerosols, paints, inks, toners, pressroom chemicals, adhesives and sealants, construction chemicals, fragrances, disinfectants, lubricants and chemical distributors industries. Altogether, their membership comprises more than **9.000 companies** across the respective sectors in Europe, the vast majority being SMEs. The calculated turnover of these companies is more than **215 billion euros** in Europe.

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DUCC's public ID number in the **Transparency Register of the European Commission** is: **70941697936-72**