Health and Environment Alliance (HEAL) – Follow-up comments to CARACAL 37 discussions on essential uses (documents 41_CA_61_2020 and 39-CA_61_2020)

6th January 2021

The Health and Environment Alliance (HEAL) welcomes the opportunity to comment on the European Commission documents relating to the concept of essential uses, which were presented and discussed at CARACAL 37 in November 2020. Responses to the specific questions to CARACAL can be found after our general considerations.

Comments regarding document 41_CA_61_2020

HEAL welcomes the overall framing and aims stated in the EU Chemicals Strategy for Sustainability (CSS) that guide the present reflection about the development of criteria to define essential uses.

The fact that the essential use concept already emerges in the context of ongoing restriction decisions under REACH (section 2.1.4 references to the microplastics and PFHxA restrictions under development) is a clear signal that there is scientific, political and societal impetus for further elaboration of this approach and that is absolutely feasible. If well-crafted and well-implemented in the context of the existing European legal framework, the concept has the potential to drive the development of safer and sustainable chemistry for the benefit of society and overall more protective chemicals management.

Considerations on the arguments listed as potential disadvantages to the development of such approach (section 2.3):

- Regrettable substitution and impaired competitiveness: in our view, the added-value of a well-crafted concept of essential use(s) should exactly allow to avoid such caveats by guiding industry in order to make more sustainable and smarter investment choices and overall contributing to a more predictable regulatory framework over the long run.

- Preventing society from benefitting from the convenience of utility of certain uses: this argument is based on the wrong assumption that the concept has not previously been carefully defined, including the numerous dimensions at play when addressing societal needs. It also wrongly ignores that people are currently not well informed about the harmful substances they are exposed to via consumer products and other channels and that such information plays an important role in consumer choices – as illustrated by recent surveys[1]. A critical aspect in this regard is that consumers assume that every single item that is on the market has undergone comprehensive safety testing – which we know is not the case – and that regulations protect them from exposure to harmful chemicals. Finally, the above listed 'disadvantage' also fails to provide a honest picture on what constitutes a benefit for consumers and society overall; indeed the perception of convenience is likely to change when

[1] A recent Eurobarometer shows two in three citizens are concerned about exposure to hazardous chemicals, less than half of them feels well informed about the potential dangers of chemicals in products, and half of them think that the current level of regulations and standards should be increased https://ec.europa.eu/commfrontoffice/publicopinion/index.cfm/ResultDoc/download/DocumentKy/83070
Belgian Mutualités Libres Survey on EDC awareness among the Belgian population, 2020 https://www.mloz.be/sites/default/files/events/17112020-resultaten-en-3.pdf

consumers are made aware of the presence of harmful substances in a product. Therefore it is impossible to make blank statements about prevention from so-called benefits without acknowledging that consumption choices are made based on safety assumptions that are not always materialised in reality and the need to further define what constitutes a benefit for society as well.

- Deterioration of the level-playing field and exports of environment and health impacts outside the EU: this argument ignores the golden opportunity for the EU to reinforce its position as a worldwide standard setter and for Europe's industry to champion and lead safe innovation, exporting it in decades to come to other regions. This is especially important in light of the ongoing transformations of emerging markets such as those of China or India.

- Limiting people's choices and *'de facto'* regulating products or people's preferences: As stated above, these arguments assume that people are fully aware of their chemical exposure via consumer products and choices and are equipped to understand the implications for health – this is simply not the case at present. Further, they ignore that the concept of essential use(s) carry significant innovation opportunities, which may result in increasing consumer choices in the future. what they consume and what is real health risks. Therefore it is impossible at this stage to make blank statements on limitations of people's choices and regulation of people's preferences.

- Finally, we are surprised that none of the arguments developed in support of 'disadvantages' fail to mention the current reality of worsening climate change, accelerating biodiversity crisis, and the increasing occurrence of chronic diseases among the world population (which is partly associated to our chronic exposure to mixtures of chemicals). It is a fact that those developments are underway. In the context of the EU Zero Pollution Ambition, they even more urgently need to be acknowledged and they require drastic changes in production and consumption patterns. In this regard, the essential use concept should be seen as a useful guide to respond to make European regulations fitter to the protection and innovation purposes in a context of multiple serious crises faced by humanity.

Considerations on the implementation of the Montreal Protocol (section 3.1)**:**

- We note with interest that *"the sectors and uses which would be considered essential materialised relatively early in the discussions of the Parties and did not change since".* Such a fact is not only illustrative of the feasibility of a pragmatic agreement on criteria for essentiality, but also – and even more importantly – of their implementation for regulatory purposes, without major hurdles.

Section on similarities and differences between the Montreal Protocol and REACH processes (section3.2)

- The background information provided in this section is very useful to understand the different processes at play and how the Montreal Protocol can inform a better use of REACH to achieve efficient, coherent and protective regulations of chemicals.

- The fact that Parties under the Montreal Protocol have nominated no uses related to luxury, convenience, leisure, cosmetics, toys or decorative products for derogations is particularly

informative. Indeed such uses for chemicals of concern are typically the ones that civil society groups have criticised in the context of derogations granted in REACH restrictions (eg long transition times for cosmetics under the microplastics restriction in the making) and authorisations (eg chromium VI authorised for plating of lipsticks cases).

- Importantly in our view, the Montreal Protocol and REACH processes share two very important features in the context of the discussion on essential use(s): the objective of eventually ending the use of the chemical concerned, and the tolerance of uses only when no suitable alternatives exist that are technically and economically feasible. This further makes the case to use the Montreal Protocol as a guide for the development of the concept in the context of the EU legal framework.

Responses to the questions to CARACAL

(1) Have there been efforts in your Member State / Association to define a concept of essential uses or a similar concept to address REACH restrictions or authorisations or in the framework of another legislation? If yes, please explain.

N/A

(2) Are you aware of scientific or other kinds of documents that address the concept of essential uses and that have not been referred to in this document or its annex?

In our view, the paper "Scientific Basis for Managing PFAS as a Chemical Class" by Kwiatkowski et al. [2] is an interesting reference to use in the present discussion.

(3) Are you aware of legislation or other regulatory procedures that use a concept like essential uses and that are not referred to in this document?

Both EU pesticides and biocides regulations foresee clear exclusion criteria based on health and environmental considerations (eg for CMR substances and endocrine disruptors) as well as limited possibilities for derogations. In our view, the current implementation of the provisions in these regulations is not satisfactory and provides a potentially interesting example of why a pre-defined agreement of essentiality criteria is important for effective and protective legislative implementation as well as regulatory predictability.

(4) What are the challenges for the use of the concept? Who will decide on essentiality for society and how can this decision be made?

In our view, a definition of essentiality is a political decision, which needs to be made on the basis of a variety of considerations. The first of such considerations is that the criteria to define essentiality must be in line with the objectives that the European Commission has set under the European Green Deal, starting with the Zero Pollution Ambition and the 'do no harm' principles. This comes in a context of major developments shaping our environment, affecting people's health and wildlife, and requiring urgent protective action (e.g. accelerating climate change and biodiversity crisis, increasing

[2] *Environ. Sci. Technol. Lett.* 2020, 7, 8, 532–543. Publication Date:June 30, 2020. https://doi.org/10.1021/acs.estlett.0c00255

occurrence of non-communicable diseases partly associated to chemicals exposures). Therefore a discussion on essentiality of chemicals should be framed in a long-term context of profound changes that threaten our health and our environment.

In practice, it means that criteria to define essentiality must have a clear objective to increase the current protection levels against hazardous chemicals. In the context of the *'unknow territory of chemical risks'* acknowledged in the CSS, HEAL is of the view that the essential use(s) concept could significantly contribute to the faster, more efficient and more protective chemicals management that is needed.

It will therefore be important to guarantee a differentiation between the function of a substance and/or a technology (eg to save life, to ensure surgery or other vital medical operation can be performed) and a set product (eg a specific device produced according to today's technological capacities). The concept must be fit to accompany safe innovation and substitution in line with progress in scientific and technological knowledge, allowing flexibility for adaptations on that basis. Finally, a successful shift of perspective to untap the potential of the concept essential will only be possible if the perception of alternatives is as broad as possible, moving away from a chemical-to-chemical approach towards one that considers practices and technologies more broadly.

(5) Could you think of examples (ideally with a short justification):

(a) where it may be easy to define whether uses are essential or not (or likely to be essential or not)?

(b) where you believe it would be important to work on applying the concept on essentiality?

We refer to the excellent study by Cousins et al.[3] referenced in the EU Commission's document as a good starting point on the differentiation of uses.

In HEAL's view, it will be important for the concept to apply to all uses of chemicals beyond those falling in the REACH regulation in order to ensure protective, efficient and coherent EU actions on chemicals across the board – in line with the objectives of the EU Chemicals Strategy for Sustainability.

(6) To what degree shall decisions be taken on the basis of pre-defined essentiality criteria only and to what degree do decisions still need case-by-case assessments?

In complement to response to (4), we believe that a high-level political agreement on criteria for essential uses will be key to the development and successful implementation of the concept. This is because in the current context, the added-value of the concept is to speed up regulation for increased protection and incentivize safe innovation, compared to existing processes, whereby regulation is slowed down and/or not protective enough due to protracted discussions on a case-by-case approach and/or a lack of information about existing and alternative uses and technologies (eg REACH authorisation processes). We also refer to our above general comments regarding section 3.1 of the EU Commission document: the Montreal Protocol experience shows that agreement on sectors and uses deemed essential was not only possible early on, but also that it was never questioned.

[3] Cousins et al., "The concept of essential use for determining when uses of PFASs can be phased out", Environ. Sci.: Processes Impacts, 2019,21, 1803-1815, https://doi.org/10.1039/C9EM00163H

(7) Are there aspects that you would consider important to investigate during the development of an essential use concept and that have not yet been mentioned?

We refer here to our above general comments in response to the arguments listed in the Commission document section 2.3 as potential disadvantages to the development of such approach.

(8) Do you have initial ideas on criteria or definitions that might help to decide whether a use might or not be essential?

See above comments related to section 3.2 of the document.

(9) What would you consider the most appropriate way to develop the concept, definitions and criteria further

We do not have preferences as regards the format chosen to further develop the concept as long as the future discussions are well-prepared (with enough forward notice and documents shared with stakeholders), focused, based on facts, and involve all relevant institutional actors in charge of policy decisions that will be affected by the implementation of the concept.

In conclusion, we thank the European Commission for the preliminary research work done as well as the background information provided to initiate this discussion. HEAL supports moving forward in the development of the concept of essential use(s) and its potential applicability in the EU legal framework, starting with REACH.

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