Health and Environment Alliance (HEAL) – Comments following CARACAL 44 discussion on options to implement the extension of the generic approach to risk management in the REACH Regulation

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The Health and Environment Alliance (HEAL) strongly supports the European Commission's commitment to extend the generic approach to risk management (GRA) in the REACH regulation under the Chemicals Strategy for Sustainability (CSS). We thank the European Commission for the preparatory work to the discussion that took place during CARACAL 44 on 23rd March (including document CA/19/2022).

With the present short comments, we would like to express some concerns regarding the implementation options proposed by the European Commission as well as the discussion that took place at the CARACAL 44 meeting.

The CSS commitment regarding the extension of the GRA approach stems from the urgent need to get the substances with properties of high concern – starting with substances that cause cancers, gene mutations, affect the reproductive or the endocrine system, or are persistent and bioaccumulative - out of the market as soon as possible in order to increase the protection of consumers as well as of the environment. The CSS also explicitly commits to extending the level of protection granted to consumers to professional users under REACH. Such commitments logically build upon a simple reality: the best protection against the effects of hazardous substances is and will always stem from avoiding their production and use in the first place.

Therefore, the departure point of the discussion is and should remain the aim for default bans of the substances with hazardous properties targeted by the CSS (whether on their own, in mixtures, or in articles) across uses rather than reopening the aim and scope already outlined in the CSS. Because the endeavor is significant, we acknowledge that a stepwise implementation can be considered based on the following two aspects: 1) targeting category 1 endpoints before category 2 and 2) establishing a clear timeframe for the gradual implementation of GRA in view of covering all articles across consumer and professional uses within a reasonable timeframe (maximum five years). However, structuring the **entire** implementation of the GRA approach around the definition of article types and use types would threaten the delivery of the protection objectives under the CSS.

In this regard, during the CARACAL 44 meeting, we were extremely surprised that the discussion revolved strongly around the issue of the suggested safety of some uses and that it left room to consider subcategories in e.g. professional uses depending on criteria that are hard to control and to measures (such as the existence of professional trainings in some industry sectors). Such a direction is not acceptable because it would change the very nature of GRA and introduce significant uncertainties and delays in the process that would cancel out the benefits of introducing the approach for health protection in the first place. The GRA implementation plan should be developed independent of the existence of sectoral legislations; as it is also not acceptable to exclude any sectors from the GRA approach under the ground that sectoral legislations exist.

Finally, we also recall that the CSS foresees to *"in the meantime, while the generic approach to risk management is not in place, prioritise all the above-listed substances for restrictions for all uses and through grouping, instead of regulating them one by one".* Therefore, the restriction roadmap already is meant to provide the transition tool to be used while the GRA approach is being developed. This

strongly makes the case to uphold an approach guided primarily by the gradual phase-in of the relevant hazard endpoints in developing the GRA.