

Joint health and environmental NGOs' comments to the update of REACH Annexes in relation to endocrine disruption properties as follow-up to the CASG-ED6 meeting

17th February 2022

The Health and Environment Alliance (HEAL), CHEM Trust, the European Environmental Bureau (EEB) and Client Earth welcome the opportunity to provide follow-up comments to the discussion that took place in relation to the update of the REACH annexes setting out the information requirements for endocrine disrupting properties at the CASG-ED6 meeting that took place on 24th January 2022.

Overall, we would like to express severe concerns at the current trajectory of this process, which reinforces previous reservations voiced about procedural choices made by the Commission to proceed with the update of the targeted annex. In the written comments submitted jointly by the Health and Environment Alliance and CHEM Trust in April 2021ⁱ, we already warned that the Commission's decision to carry out a cost-benefit study seems at odds with the urgent need to proceed with the update at the service of improved EDC identification and ultimately the EU's commitments for increased protection of human health and the environment against EDCs under the EU Chemicals Strategy. We highlighted the specific context of the current lack of data on EDCs, the scientific challenges for EDC identification due to a lack of appropriate test methods, the importance of expert judgement, and we urged the Commission to take those important specificities into account before proceeding with any cost-benefit study – should it decide to do so.

Unfortunately, based on the presentation given by the Ricardo consultancy during the CASG-ED meeting of 24th January, it appears that the above concerns have not been considered properly.

We would therefore like to highlight the following points:

- **Overall, the consultants' presentation put a very heavy emphasis on economic costs, while no efforts were made to explore health and environmental implications – and related costs - of exposure to EDCs.** We acknowledge that monetizing the health and environmental impacts of EDCs is not an easy task due to the very specificities of those compounds (low-dose effects, non-monotonic dose responses, large time lags between exposure and impacts sometimes across several generations...); this is precisely why we originally advised against carrying out such cost-benefit exercise. Keeping these challenges in mind, there are, however, serious and reliable publications on this aspect, which are publicly available and that the consultants could have easily found with a simple literature search as part of the duties falling within their contract.ⁱⁱ Furthermore, the European Commission is currently supporting a cluster of eight research projects specifically focused on the improvement of EDC testingⁱⁱⁱ that brings together world references in the field of ED research and could easily have been reached out to and consulted for the purpose of the exercise. In any case, the difficulty to gather quantitative data on both costs and benefits cannot justify a mere focus on the economic costs that will potentially stem from the IR update. A qualitative approach should then be favoured.
- **In this context, it is of utmost importance that the consultants and the Commission transparently explain how they intend to proceed when weighing the different pieces of**

evidence gathered for the purpose of the study against one another. As the Commission is well aware, it will always be easier to find out information about the monetary costs of carrying out additional tests than to gather harmonized data on health effects and environmental pollution as a result of EDC exposure. It will be even more difficult to gather harmonized data assessing the benefits that would stem from avoided EDC exposure. This is partly because the effects of EDC exposure may take years or decades to materialize. This important aspect needs to be accounted and mitigated for, and it again makes the case for a qualitative approach.

- **The above-mentioned point is of particular importance since the consultants' presentation at the CASG-ED meeting raised concerns about the quality of the evidence retained for the study so far and the consultants' own ability to exert critical judgement in deciding what to keep in and what to exclude to adequately assess the impacts.** This perception is based on the presentation of supporting evidence retained so far and included in the consultants' PowerPoint presentation during the meeting. By way of example: slide number 7, in which industry contributions but none from civil society groups were mentioned as part of the CARACAL evidence; or slide number 8, which highlighted the following study: Borgert, C.J., Baker, S.P. and Matthews, J.C. 2013, Potency matters: thresholds govern endocrine activity. *Regulatory Toxicology and Pharmacology*, 67(1). The latter industry-funded study makes strong assumptions on EDC modes of action that a large number of world-renowned independent experts^{iv} in the field would largely disagree with and that have important implications for the direction of the process at play. Due to the long history of scientific and political controversies in relation to the scientific identification of EDCs, the European Commission cannot afford the credibility risk that the present study would not be based on high-quality scientific evidence. In relation to this point, full transparency about the design of the study is necessary if it is to move forward; this includes the full outline of existing uncertainties as well as of the assumptions made by the consultants and the justifications for doing so (e.g., regarding estimates used on the number of substances to be identified as EDCs). This is all the more important as Europeans' taxpayers' money is being used to finance this study.
- **Furthermore, during the CASG-ED meeting, we were very surprised to hear from several Member States experts that they did not appear to have been consulted as part of the online focus groups organized by the consultants.** This reinforces the concerns expressed above and appears as a missed opportunity for evidence gathering. Because EDC identification is so much about experts' judgements and Member States experts have built a unique knowledge base through the assessments that they have carried over the last decade, they are a primary source of information and should therefore be an important information and guidance provider in the development of the present study. When it comes to the issue of the costs of carrying out specific tests, we note with concern that the information used and presented during the CASG-ED meeting is derived from an outdated OECD list, which is itself based on enquiries carried out towards contract research organisations in order to get an indication of costs for individual tests. This is not acceptable and this could have been spotted and rectified through in-depth exchanges with Member States' experts, who are able to provide relevant information on the basis of their experience, including nuances that relate to the overall decreasing price trends as studies get replicated over time (the latter aspect is currently not reflected in the consultants' approach).

Based on the precedent points, we would like to repeat our severe concerns about the current approach to the update of the REACH annexes that pertain to information requirements for EDCs and its potential consequences for the future of EDC identification. On numerous occasions, our organisations have repeated that the primary purpose of this exercise should be to allow for the provision of increased and higher-quality information about substances under assessment for their endocrine disrupting properties. This will not only contribute to better EDC identification under REACH, but it will also serve important efficiency gains in further EDC-related regulatory processes relying on this information across sectors.

At this point, the progress in the development of the cost-benefit study that will play an important orientation role for how the Commission will proceed with the two options on the table does not appear to go in this direction. **The CASG-ED, as a collective body of experts, has already invested significant time to support the European Commission, including through the provision of very detailed written inputs for the redrafting of the REACH annexes. As part of this process, health and environmental civil society groups alongside a large number of Member States experts have expressed clear support for option 2 to be used as a starting point for the ED-IR overhaul.**

We regret that the study under preparation appears to undo this important work rather than build upon and add value to it. We urge the Commission to take steps to adapt the process accordingly and guarantee that the update can proceed as soon as possible based on the highest quality expert advice.

ⁱ Joint Health and Environment Alliance (HEAL) and CHEM Trust comments on draft discussed at 4th CASG ED meeting of 22nd March 2021 on: European Commission proposal for update of the REACH Annexes in relation to endocrine disruption properties, April 2021, available at: <https://www.env-health.org/wp-content/uploads/2021/04/2021.04.26-HEAL-CHEMTrust-Comments-IR-April2021-draft-final.pdf>

ⁱⁱ Recent examples include:

Trasande L, Zoeller RT, Hass U, Kortenkamp A, Grandjean P, Myers JP, DiGangi J, Hunt PM, Rudel R, Sathyanarayana S, Bellanger M, Hauser R, Legler J, Skakkebaek NE, Heindel JJ. Burden of disease and costs of exposure to endocrine disrupting chemicals in the European Union: an updated analysis. *Andrology*. 2016 Jul;4(4):565-72. doi: 10.1111/andr.12178. Epub 2016 Mar 22. PMID: 27003928; PMCID: PMC5244983.

Rijk I, van Duursen M, van den Berg, Health costs that may be associated with Endocrine Disrupting Chemicals An inventory, evaluation and way forward to assess the potential socio-economic impact of EDC-associated health effects in the EU, report commissioned by the Dutch Ministry of Infrastructure and the Environment, 2016, https://www.uu.nl/sites/default/files/rijk_et_al_2016_-_report_iras_-_health_cost_associated_with_edcs_3.pdf

Grandjean, P., Bellanger, M. Calculation of the disease burden associated with environmental chemical exposures: application of toxicological information in health economic estimation. *Environ Health* 16, 123 (2017). <https://doi.org/10.1186/s12940-017-0340-3>

ⁱⁱⁱ EURION, European cluster to improve identification of Endocrine disruptors, <https://eurion-cluster.eu/>

^{iv} We believe that the following scientific consensus statement is an important reference on this point: Solecki R, Kortenkamp A, Bergman Å, Chahoud I, Degen GH, Dietrich D, Greim H, Håkansson H, Hass U, Husoy T, Jacobs M, Jobling S, Mantovani A, Marx-Stoelting P, Piersma A, Ritz V, Slama R, Stahlmann R, van den Berg M, Zoeller RT, Boobis AR. Scientific principles for the identification of endocrine-disrupting chemicals: a consensus statement. *Arch Toxicol*. 2017 Feb;91(2):1001-1006. doi: 10.1007/s00204-016-1866-9. Epub 2016 Oct 6. PMID: 27714423; PMCID: PMC5306068.