



CHEMTrust

Protecting humans and wildlife
from harmful chemicals

Consultation Response July 2019

Response to Commission Roadmap “Fitness Check on endocrine disruptors”

General comments:

CHEM Trust welcomes the opportunity to provide comment on the European Commission roadmap for the fitness check on endocrine disruptors. We welcome the focus on protection of vulnerable population groups that are particularly sensitive to endocrine disruptors, and the particular attention to legislation that does not contain specific provisions for EDCs e.g. legislation of toys, cosmetics and food contact materials.

At the same time, we are very concerned that this new ED fitness check will result in an additional delay in the protection of the European citizens and the environment from harmful effects due to exposure to endocrine disruptors. This is even more concerning as the European Commission has failed to deliver the protective measures as defined by the 7th European Environment Action Programme (7th EAP) in order to ensure minimisation of exposure to endocrine disruptors.

CHEM Trust want to emphasize that gaps in various pieces of EU legislation regarding endocrine disruptors have already be pointed out in several EU Commission reports, roadmaps etc., and by MS and stakeholders already in the process of establishing criteria and providing inputs to a new and updated EU strategy on Endocrine Disruptors during the work under DG Environment 2010-2013. It is therefore unclear whether this fitness check will identify new important issues to take into account other than already identified by the different evaluations referred to in Section B and the “State of the Art Assessment of Endocrine Disruptors” from 2011¹.

It is high time that the EU Commission takes immediate action and reflects that European citizens are increasingly and justified concerned because scientific research over many years has revealed increasing evidence that EDC exposure can adversely affect wildlife (as was already known over 20 years ago)² and can contribute to several serious human diseases and disorders^{3,4}. These actions to reduce exposure to EDCs can be based on already available scientific literature as described in a recent report commissioned by the European Parliament⁵.

In order not to further delay the process, it is therefore extremely important that the EDC fitness check includes a thorough analysis of all relevant EU legislation as regards protection against endocrine disruptors, including for all types of consumer products, and on this basis set up a horizontal approach for identifying and controlling endocrine disruptors across all relevant legislations with detailed proposals for revision of provisions or new legislation. The new approach should also ensure that future provisions on EDCs will be fit for purpose for supporting the goal of a non-toxic environment and a clean circular economy. Only then can a high level of protection for health and environment be achieved.

¹ http://ec.europa.eu/environment/chemicals/endocrine/pdf/sota_edc_final_report.pdf

² <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2721670>

³ CHEM Trust report: No Brainer: The impact of chemicals on children`s brain development: a cause for concern and a need for action, March 2017. <http://www.chemtrust.org/brain>

⁴ Gore AC, Chappell VA, Fenton SE, Flaws JA, Nadal A, Prins GS, et al. 2015. EDC-2: The Endocrine Society's Second Scientific Statement on Endocrine-Disrupting Chemicals. *Endocr. Rev.* 36:E1–E150; doi:10.1210/er.2015-1010

⁵ [http://www.europarl.europa.eu/RegData/etudes/STUD/2019/608866/IPOL_STU\(2019\)608866_EN.pdf](http://www.europarl.europa.eu/RegData/etudes/STUD/2019/608866/IPOL_STU(2019)608866_EN.pdf)

Specific comments:

As regards the horizontal approach and criteria for the identification of endocrine disruptors:

The 7th EAP defines that the EU should develop harmonised hazard-based criteria for identification of endocrine disruptors. EU-criteria for identifying endocrine disrupting biocides and PPP that are based on the WHO-definition are already adopted together with a guidance document on the identification of ED-substances. However, the EU-criteria for biocides and PPP are requiring an unreasonably high level of evidence for the endocrine disrupting properties before a substance can be identified as an ED. And further, data availability is much higher for biocides and PPP than for other types of chemical substances and products.

For many chemical substances data on endocrine disrupting properties are, however, often inadequate or even lacking and this fact should be taken into account when considering implementation of a horizontal approach for criteria on endocrine disruptors. Adequate test methods for identification of many endocrine disrupting properties are also lacking. It is, therefore, important to implement an approach that ensures fully transparency about which chemicals have been evaluated for ED-properties and the outcome of the evaluation.

At the same line it should also be considered to implement the full WHO-definition into the EU-legislation as the WHO-definition also includes a definition of a potential endocrine disruptor. This will also align the approach to the CMR legislation.

As regards regulatory consequences for endocrine disruptors

Chemical substances should be identified as EDCs based on their intrinsic hazardous properties and not based on which regulation it is covered by. However, it should be remembered that the existence of different regulatory approaches for ED substances depending on the different pieces of legislation is often a deliberate choice to have different types of risk management for chemical substances and products that reflects the different types of applications and uses. However, there are also areas of regulation where EDCs are not considered, such as food contact materials.

As regards data collection and methodology

CHEM Trust propose the following issues that the fitness check should consider:

- Critical windows of susceptibility of exposure during development, both for humans and environmental animal species
- The full enforcement of the precautionary principle
- That regulatory measures are adopted for all sectors that take into account the risk of combined exposure to EDCs
- The need for updating of the data requirements in line with developing science
- That the process and outcome of the ED-evaluation of substances is transparent
- The shortcomings of some of the evaluations mentioned in the Road Map, in particular
 - the recent review of the Cosmetics regulation with regards to endocrine disruptors did not include the risk of combined exposure to endocrine disruptors. Further, the concern expressed by the SCCP as regards data availability should be reflected.
 - the impact assessment for PPP and biocides did not include the benefits for human health and environment. A proper impact assessment with regard to ED assessment needs to include the human and environmental benefits (economic) in order to

adequately assess the impact of the regulation where the primary goal is to protect health and environment.

In CHEM Trust’s view EDCs should be treated as non-threshold substances equivalent to chemicals with PBT/vPvB properties. This is due to increased uncertainties in the risk assessment and the potential to lead to serious and irreversible effects in current and future generations (see CHEM Trust briefings)^{6,7}.

CHEM Trust is a part of the EDC-Free Europe coalition. These comments are supplementary to those submitted by EDC-Free Europe.

Pia Juul Nielsen, for CHEM Trust, 10th July 2019

⁶ <http://www.chemtrust.org/wp-content/uploads/CHEM-Trust-Briefing-on-REACH-EDC-reviewFINAL.pdf>

⁷ <http://www.chemtrust.org/wp-content/uploads/Hazard-v-Risk-a-CHEM-Trust-position-paper-Nov2013.pdf>