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HEAL response to Germany's proposal to classify trifluoroacetic acid (TFA) as toxic for reproduction and (very) persistent, (very) mobile and toxic - CLP

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General comments

The Health and Environment Alliance (HEAL) welcomes the opportunity to comment on Germany's proposal to classify trifluoroacetic acid (TFA) as a presumed human reproductive toxicant (Repr. 1B; H360fD) and (very) persistent, (very) mobile and toxic (PMT; EUH450 and vPvM; EUH451) and fully supports this initiative.

Trifluoroacetic acid (TFA) is an ultra-short-chain PFAS compound, which is highly water-soluble and has been detected ubiquitously in surface water, groundwater and even drinking water [1-3]. The pervasive occurrence of TFA leads to the widespread exposure of humans and wildlife to this PFAS chemical. TFA is a precursor, intermediate and transformation product of several longer chain PFAS and is often presented as having negligible risks for human health and the environment, despite its omnipresence and mounting scientific evidence on chronic effects [4-6].

We welcome the current classification initiative for TFA in application of the EU regulation on classification labelling and packaging of substances and mixtures (CLP Regulation) and would like to thank the German dossier submitters for the preparation of the comprehensive and conclusive CLH report.

Comments on the proposed classification

The CLH dossier presents detailed information, and the methodology used to report on the scientific evidence available on different classification criteria is very clear and transparent.

- **Reproductive toxicity:** We agree that based on the observed effects such as eye malformations in rabbits, it is appropriate to classify TFA as a presumed human reproductive toxicant due to adverse effects on development of the offspring. Considering the evidence for fertility effects in rats, such as impaired sperm quality, we agree that the available data is sufficient to conclude on a suspected effect of TFA on fertility. We would also like to highlight that due to differences in the sperm concentrations of between rodents and humans, a statistically significant change in sperm count in a rodent study is considered to be indicative of a potential effect on fertility in humans and even small decreases in sperm concentration could move some men into the infertile or sub-fertile range [7]. Additionally, we observe that for neither developmental nor fertility effects of TFA there is unequivocal evidence that the observed effects are secondary to parental toxicity.

  We would also like to underline that clear evidence from high-tiered studies including extended one-generation toxicity studies, prenatal developmental toxicity studies and non-guideline

developmental toxicity studies with experimental animals is presented in the CLH report. The results of these studies clearly possess high relevance for the lifelong and multigenerational exposure to TFA that EU citizens and wildlife are subject to.

- **PMT/vPvM:** We agree that the data presented in the CLH report shows that TFA is very persistent in freshwater, freshwater sediment and soil. Due to a lack of degradation, no meaningful degradation half-life could be calculated for the investigated environmental compartments.

  We are also in agreement that sufficient evidence is presented to show that TFA is a very mobile substance, due to its very low log Koc values of the TFA anion from independent adsorption/desorption studies. Additionally, we note that the very high persistence and mobility of TFA is also evident in the ubiquitous occurrence and continuous increase in concentration of the substance in water bodies, including those in remote locations [8].

  Finally, we agree that there is strong evidence that TFA is toxic, as it fulfils the classification criteria for reproductive toxicity Cat. 1B (see also specific comments above).

Based on the above, HEAL supports the proposed classification: Reproductive toxicity Cat. 1B (H360fD; Suspected of damaging fertility; May damage the unborn child), Persistent, Mobile and Toxic (PMT, EUH450; Can cause long-lasting and diffuse contamination of water resources) and very Persistent, very Mobile (vPvM; EUH451; Can cause very long-lasting and diffuse contamination of water resource).

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