

Exclusion of trifluoroacetic acid (TFA) from the scope of the Proposal

General Comments:

As the supporting unit of ODS Alternatives Engineering & Technology Centre of China and Zhejiang Branch of National Pesticide R&D South Centre, Zhejiang Research Institute of Chemical Industry Co., Ltd is a research & development enterprise in the fields of fluorine chemical, pesticide chemical and fine chemical, has the State Key Laboratory of Fluorine Greenhouse Gases Replacement and Control Treatment. We manufacture PFAS substances such as trifluoroacetic acid to meet the unique requirements for application properties in the fields of pharmaceuticals, pesticides, dyes, and materials processing. As trifluoroacetic acid provides essential uses for downstream products, we request that exclusion of trifluoroacetic acid (TFA) from the scope of the Proposal.

Reasons are listed below:

(1) TFA is not a PBT, vPvB or PMT substance

According to the REACH registration dossier and Chemical Safety Report (CSR)^[1], TFA is a persistent substance, but TFA does not meet the criteria either for toxicity or for bioaccumulation according to the EEAP 2022 Assessment Report^[2] ii (Page 278), this substance does not fulfil the criteria for a PBT or vPvB substance under Annex XIII REACH. Neither does it raise equivalent levels of concern under Article 57(f) REACH.^[3]iii

(2) TFA is low in toxic and unlikely to cause adverse effects

The mammalian toxicity of TFA and human exposures are reviewed by Wolfgang Dekant et al^[3], the results of the study showed that: (i) The potential of TFA to induce acute toxicity is very low. (ii) Oral repeated dose studies in rats have identified the liver as the target organ with mild liver hypertrophy as the lead effect. (iii) Biomarker analyses indicate that TFA is a weak peroxisome proliferator in rats. (iv) TFA administered to rats did not induce adverse effects in an extended one-generation study and in a developmental toxicity study or induce genotoxic responses. These four

points indicate that TFA has low toxicity to mammals.

The EEAP 2022 Assessment Report ^[2] (Page290) states that TFA has a no observed effect concentration (NOEC) of 2.5 mg a.e. L⁻¹ (2,500,000 ng L⁻¹), which is particularly low in toxicity to aquatic organisms.

The EEAP 2022 Assessment Report ^[2] (Page25 and 259) also concludes that “based on projected future use of these precursors of TFA [incl. HFC/HFO], no harm is anticipated” and that “TFA is unlikely to cause adverse effects out to 2100”.

(3) Persistence alone is not sufficient for grouping PFAS

The EEAP 2022 Assessment Report ^[2] (Page 278) unequivocally cited a common agreement among the majority of experts that “all PFAS should not be grouped together, persistence alone is not sufficient for grouping PFAS for the purposes of assessing human health risk, and that the definition of appropriate subgroups can only be defined on a case-by-case manner.” In addition, the majority opinion with respect to toxicology was that “it is inappropriate to assume equal toxicity/potency across the diverse class of PFAS”.

Reference□

ⁱ [1] Chemical Safety Report (CSR).

ⁱⁱ [2] Environmental Effects of Stratospheric Ozone Depletion, UV Radiation, and Interactions with Climate Change, EEAP 2022 Assessment Report.

ⁱⁱⁱ [3] W. Dekant, R. Dekant. Mammalian toxicity of trifluoroacetate and assessment of human health risks due to environmental exposures, *Arch. Toxicol.* **2023**, 97, 1069-1077.