Comment on European Union about PFAS proposal

In recent years, the EU has made a lot of efforts in the management and control of global fluorine-containing pollutants pollution, and we will actively cooperate with the PFAS control work. For this year, Denmark, Germany, the Netherlands, Norway, Sweden five countries submitted to the European Chemicals Agency (ECHA) for perfluorinated or polyfluoroalkyl substances (PFASs) REACH regulatory restrictions. We believe that this proposal is an excessive definition of PFAS and is not scientifically rigorous enough, and once implemented, this proposal will have a fatal blow to many industries such as global fluorine chemicals, chips, and lithium batteries.

(1)The proposal is unclear about the amount of substances contained in PFAS

As a formal and strictly legal proposal, the types and quantities of substances to be restricted should be specified. The proposer said in the press release that the proposal contains "roughly 10,000" substances, which is itself a vague number, meaning that the EU proposer itself cannot say how many substances are contained in its so-called "PFAS." Also based on the OECD's definition of PFAS, relevant expert studies have found that more than 12,000 substances can be retrieved in the US Environmental Protection Agency EPA's "PFSA master list" and more than 6 million substances can be retrieved in the latest PubMed. However, no one person or organization has been able to say exactly how many substances are contained in the so-called "PFAS" so far, and the current human understanding of PFAS is far from enough.

(2)The definition of PFAS in the proposal is not clear enough

In the proposal, substances with the $-CF_2$ and/or $-CF_3$ structural formula are generally defined as PFAS. The concept itself is not clear enough. When faced with a specific fluorine-containing substance, it is difficult for the public to know whether it is a "PFAS" under the proposal, and how can they know whether it is a controlled substance? This will certainly bring great uncertainty to the implementation of the bill and cause confusion in management. Furthermore, no scientific study has ever defined substances with the $-CF_2$ and/or $-CF_3$ structural formula as PFAS, and the broad definition adopted by EU clearly lacks scientific rigor.

(3)The current research on the toxicity of fluorine-containing substances is not deep enough to generalize

These experts believe that human health risk assessment for PFAS is complicated by a number of factors, including but not limited to: (1)there is not a clear understanding of which PFAS may be relevant for potential human health risk assessment and no consensus definition of what is or not a substance within the PFAS family; (2) there is sparse information on PFAS toxicity and human exposure that precludes an chemical-specific evaluation of the vast majority of PFAS; (3) most human exposures will be to an unknown mixture of PFAS; and (4) results of toxicity tests often lack concordance among assays in animals and observations in humans, and extrapolation from animal data to human relevance (for example, due to species-specific pharmacokinetics and pharmacodynamics and/or mechanisms of action) is highly uncertain. Therefore, an appropriate grouping approach to PFAS is a necessary first step to inform regulators and assess the risks to the general population of legacy and/or current and future alternatives to PFAS, rather than a

blanket definition of PFAS for substances containing -CF_2 and/or -CF_3, which differ significantly between their physicochemical properties and toxicity. In the case of insufficient research on its toxicity, it is obviously unfair to conduct partial control, which will seriously hinder the normal industrial development process.

(4)PFAS control should be grouped based on the results of rigorous toxicity studies

Chemistry itself is an experimental science, and the scientific control measures are to conduct in-depth research on the toxicity of substances and then control them. The expert noted that risk does not scale predictably with production/use, as risk is related exclusively to hazard and exposure. compound-specific MOA or adverse outcome pathway (AOP) information is “the gold standard” critically necessary for grouping of PFAS for the purposes of human health risk assessment. Ideally, PFAS groupings should be based only on common toxic MOAs and/or target organs. Only those PFAS that affect the same target organ/tissue/system should be grouped and assessed for dose additive or response additive approaches. Unfortunately, these data are the least likely to be available for the majority of PFAS. Added complexity noted is that individual PFAS are likely to have different MOA/AOP across tissues/organs. It was acknowledged that toxicity, bioaccumulation, toxicokinetics, and exposure profiles would vary among PFAS and therefore, those characteristics should be considered when assessing human health risk. Grouping all PFAS together as “persistent” was not supported as practical nor appropriate for assessing human health. The approach of scientific rigor should be based on research findings, the management of a substance or a group of substances, rather than taking for granted that fluorine-containing substances are equally toxic through similar reasoning.

In general, "all hazardous substances" should not be grouped together, persistence alone is not sufficient to group hazardous substances in order to assess human health risks, the classification needs to be appropriate, and the nature and definition of the classification can only be determined on a case-by-case basis. There is currently no agreement on a single cluster strategy that meets all regulatory or public health risk assessment purposes.