

Comment on the EU PFAS Restriction Proposal

On behalf of Zhejiang Juhua Co., Ltd, we would like to greet ECHA and the five countries of the PFAS restriction proposal (hereinafter referred to as the "Proposal"). We have been strictly complying with the domestic and international regulations, and have been conducting strict self-examination on the compliance of products exported to the EU in order to meet the requirements of the EU chemical regulations, including REACH.

We agree with and support the comment of Conference of Fluoro-Chemical Product Japan(FCJ), recognizing its scientific and professional nature, as well as the authenticity and reliability of the arguments and data therein. We strongly recommend that the Review Committee of Experts carefully study this comment (see Reference 1 for details).

In addition, the following new comments are added:

I. Jurisdiction of the proposal is not clear

Since PFAS is widely used around the world and the scope is very different, as a proposal of European law, if individuals, enterprises, organizations and other relevant parties (hereinafter referred to as "relevant parties") are not clear about how many substances are covered by the proposal and what they are, they will not be able to comply with the proposal effectively due to the confusion in their understanding of the

scope of the proposal.

1. Unclear definition of restricted substances. PFASs are used by many scientists, organizations, and countries, and different definitions have been given to refer to the scope of different substances (for details, see Reference 2). The use of Per- and polyfluoroalkyl substances (PFASs) on the cover page of the proposal will cause confusion to the parties concerned, and it is necessary to redefine the substances involved in the proposal by using more rigorous and clearer terms and expressions, and it is suggested that they can be defined as EU-PFASs or 5C-PFASs.

2. The scope of restricted substances is not clearly defined. The Brussels press conference on February 7, 2023 mentioned that the proposal covers about 10,000 PFASs; while the public comment session on April 5, 2023 mentioned that the proposal covers more than 10,000 PFASs; the introduction on the first page of the proposal mentions that PFASs are a group of thousands of major man-made substances; and the proposal is not clear on the scope of restricted substances. PFASs are a group of thousands of major man-made substances; the Scope section on the second page of the proposal text mentions that the definition of PFASs is consistent with the OECD definition of PFASs to be released in 2021, which includes more than 10,000 PFASs, including a number of subgroups of PFASs that are fully biodegradable. Therefore, from the expressions of the proponents on different occasions and in different parts

of the proposal itself, it can be seen that the scope of substances to be governed by the proposal ranges from thousands to tens of thousands, and the different expressions will lead to the public not being clear about how many substances are covered by the proposal and exactly what substances.

3. Excluded substances are not clearly defined. In the Scope section on the second page of the proposal, PFASs that are excluded from the proposal are described as see para below, which does not list the exceptions and makes the scope boundary unclear. It is recommended that the referenced description of see para below be deleted, and that the excepted substances be listed directly, with an indication of whether or not the exceptions are a complete and exhaustive list. Additionally, the OECD 2021 definition itself is unclear because it is described by positive and negative examples, does not say whether it is a complete exclusion or not, and its Executive Summary states that the term PFASs is a broad, overarching, and non-specific term that is not informing that the compounds are hazardous or non-hazardous, but rather is used solely to communicate that the compounds under the term The compounds under this term share the same characteristics of perfluoromethyl or methylene carbon structure (see References 3 and 4 for details). The proposal cites this definition, and by the definition it is determined that the substance itself is risky, which is beyond the OECD experts' own knowledge and

original intent.

In summary, for the above reasons, for the bill, the relevant parties will not be able to effectively comply with the implementation. The proposal should clarify the substances involved and provide a breakdown of the substances to be governed including but not limited to substance name, CAS, EC number, molecular formula, structural formula, persistence, bioaccumulation and (eco)toxicological properties.

II Contradiction with REACH principles

The proposal will control all PFAS as a single group. In following this grouping approach, the proposal will restrict PFAS that have not been risk assessed and for which there is no evidence of unacceptable risk, which is contrary to the provisions of Article 68(1) of REACH. The actual scope of application of Article 68(1) of REACH: the need for society as a whole to work together to address the unacceptable risks to human health and the environment, in particular, the need to address the unacceptable risks to human health and the environment. Please note in particular that the "risk" must be proven to exist and not "feared/presumed/likely to exist".

1. The main concern for all PFASs and/or their degradation products within the scope of the proposal, as mentioned in Concern section on page 1 of the proposal, is the very high persistence, as well as further concerns about bioaccumulation, mobility, potential for long-range

transport, accumulation in plants, global warming potential and (eco-)toxicological effects. Of these, persistence applies to all PFAS, but the other properties can only be relevant for some specific compounds. The proposal does not sufficiently examine and clarify the following queries: (1) The relationship between persistence and risk, i.e., must a persistent substance necessarily carry a risk? (2) Do all PFAS substances have the same persistence? In fact, the results of a study conducted by a panel of independent experts on the grouping of PFAS for human health risk assessment showed that: (1) many experts agree that "all PFAS" should not be grouped together; (2) persistence alone is not sufficient for PFAS to be grouped together and used for human health risk assessment, and that defining appropriate subgroups can only be done on a case-by-case basis; and (3) persistence is not necessarily the same for all PFAS. Defining appropriate subgroups can only be done on a case-by-case basis; (3) It is inappropriate to presume that substances in differentiated PFAS groups have the same toxicity, and most of the scenarios used today suffer from overestimation of risk (see Ref. 5 for details).

2. As confessed in Scope section on page 2 of the main text of the proposal: the PFAS to be restricted cover about 10,000 substances with very different physical, chemical and biological properties. As such, this broad scope does not take into account the specific, varying characteristics of different individual PFAS or subgroups of PFAS, and

therefore, the lack of a targeted regulatory objective will consume significant administrative resources that will be difficult to effectively manage for regulatory risk purposes. In fact, other than the very high persistence claimed by the proposal, no other hazardous attributes common to PFAS have been identified. The proposal contains evidence on only some substances of PFAS (mainly some long-chain PFAS) and lacks data on other PFAS substances/subgroups, as well as lacks sufficient justification why the conclusions for some PFAS can be generalized to apply to all PFAS covered by the proposed restriction.

III. Lack of sufficient data for economic and social analysis

We believe that the proposal has only studied 14 sectors and/or applied uses, which is far from sufficient for the wide range of PFAS uses, and that the proposal has not sufficiently estimated the socio-economic impacts involved, and that further scientific research should be carried out. As stated in Article 68(1) of REACH, any such decision should take into account the socio-economic impact of the restriction, including the practicality of alternatives. Therefore, when proposing the restrictive measures described in the proposal, each use should be carefully investigated and informed of the risks identified before taking harmonized action.

1. In Socio-economic analysis on page 2 of the proposal, it is mentioned that the submitter of the proposal has identified the major uses

that use and emit the maximum amount of PFASs, discussed in detail the 14 sectors and/or applications, and made emission estimates. With regard to PFAS uses, we believe that the proposal has not adequately collected information on the uses, and that a more extensive and in-depth study in a scientific manner is needed for the proposal to become a bill. In addition, the use of emission projections as the only indicator, without considering the role of natural decomposition, is extremely unserious. As recognized in Concern section on page 1 of the main text of the proposal, PFASs are a group of thousands of major man-made substances that are widely used in the EU. Therefore extensive, in-depth research needs to be rigorously carried out. For example, some scholars have studied 200 applications and sub-applications and more than 1400 PFAS substances, but the authors do not yet consider their research to be sufficient, and further research is needed on a larger number of applications (see Ref. 6 for details).

2. On page 28 of the proposal body, it is acknowledged that "for the majority of PFAS no, or insufficient, data on bioaccumulation behaviour are available" and therefore the available data on the bioaccumulation potential of PFAS are not sufficient to confirm the bioaccumulation of all PFAS in the environment and more research is needed.

3. The proposal lacks criteria and process descriptions for how to form specific exemptions. The proposal should improve the types and

criteria of exemptions, clarify the definition of essential uses and judgment methods, and make more detailed arrangements for exemptions, such as what some researchers have suggested: withdrawal of PFAS should be carried out in different trajectories according to different chronological order and priority, and not in one go (for details, see Ref. 7).

IV. Certain conclusions are not consistent with scientific facts

1. Concern section on page 1 of the proposal body states that "Environmental concentrations will increase when PFAS substances and their degradation products continue to be released into the environment because mineralization under natural conditions does not occur for PFASs within the scope of this proposed restriction." This is not consistent with the scientific facts, and in fact studies have shown that low temperature mineralization degrades perfluoroalkyl carboxylic acids, which can be extended to degrade other perfluoro and polyfluoroalkyl substances, and that the degradation is rapid, is a mild condition of defluorination, and will fundamentally solve the environmental problems of fluorinated substances (see Ref. 8 for more details). Studies on the thermal decomposition mechanism of perfluoroalkyl ether carboxylic acids and short-chain perfluoroalkyl carboxylic acids also illustrate the effectiveness of pyrolytic degradation of PFAS (see Reference 9 for details).

2. Problem identification section on page 13 of the proposal text states that "PFASs within the scope of the proposal are either highly persistent themselves or degrade in the environment to become highly persistent PFASs, a key hazard characteristic common to all PFASs in the proposal. ". This is inconsistent with the scientific fact that persistence is not necessarily a health risk, and that the health risk to humans is whether or not they can enter cells. For example, some studies have shown that fluoropolymers are practically insoluble in water and do not migrate over long distances. With molecular weights greater than 100,000 daltons, fluoropolymers cannot pass through cell membranes and are not bioavailable or bioaccumulative, and PTFE in particular is a safe substance (see Ref. 10 for details).

3. The section on Fluorinated gases on page 32 of the proposal text mentions that "some fluorinated gases (e.g., some HFOs) ultimately degrade to PFAAs, such as TFA or PFBA (Annex B.4.1.3.2), and these gases also increase the risk of total exposure to PFAAs ". This is not consistent with scientific facts, there are studies that show that second generation refrigerants, third generation refrigerants, and fourth generation refrigerants can form trifluoroacetic acid (TFA), and that F-gas emissions break down into TFA in the atmosphere, and that although TFA is has no obvious degradation pathway and can accumulate in some bodies of water, it will not negatively impact human health and the

environment before 2100 (for more details, see Refs. 11, 12).

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