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Comment on Proposed Restriction of PFAS

Conference of Fluoro-Chemical Product Japan (FCJ)

On behalf of chemical manufacturers, we, Conference of Fluoro-Chemical Product Japan (FCJ), have been working tirelessly to comply with national chemical regulations. We have supported EU's ambitious attempts to reduce risks from hazardous substances and have sincerely responded to actual measures to meet the requirements of EU chemical regulations such as REACH.

However, we believe that the proposed restriction of PFAS (Per- and Polyfluoroalkyl substances) proposed by 5 European countries is an excessive measure because it restricts more than 10,000 of organofluorine compounds (PFAS) on the grouping basis that they are persistent as substances of concern equivalent to the already regulated PFOS and PFOA.

Therefore, we intend to present the following views at the public consultation of ECHA, to which is one of the actions FCJ recommends.

（1）Concerns about inconsistencies in the proposed restriction

Article 68 (1) REACH refers to the scope of the restrictions, which regulates unacceptable risks to human health or the environment that need to be addressed by society as a whole.

The proposed restriction lists persistent chemicals (which may remain in the environment longer than any other man-made chemical), bioconcentration, mobility, the possibility of long-distance transport, accumulation in plants, the possibility of global warming, and toxicological effects as concerns and reasons for the restriction. Of these, persistent is applicable to all targeted organofluorine compounds (PFAS), but other concerns are related to some compounds.

Persistency common to all organofluorine compounds (PFAS) can be rephrased as "high durability" by focusing on its advantages, however, we believe that it is not appropriate to regulate this property alone as an unacceptable risk to human health or the environment. In addition, it is not appropriate to apply the concerns about some fluorinated compounds, such as bioconcentration potential and toxicological effects, by grouping all organofluorine

compounds (PFAS) together, and if the need for new regulations is to be considered in the future, the risk of each substance should be quantitatively assessed and discussed.

Hereafter, we respectfully submit our views on the proposed Restriction of PFAS and express its concerns that restriction would contravene the applicable European and international rules and agreements for the following reasons:

1. The proposed Restriction would hinder the achievement of the European Green Deal

PFASs have properties such as repelling water and oil, being resistant to heat, chemicals, and not absorbing light, and have been widely used in water repellents, surface treatment agents, emulsifiers, fire extinguishers, coatings, etc., and in a wide range of industrial applications such as semiconductors, automobiles, and batteries. Many of these applications and uses are considered "essential uses".
The applications in which PFAS are used are also critical for the European Green Deal – that is comprehensive initiative that includes a range of policies in different areas aiming at make Europe climate-neutral by 2050. For example, the Horizon Europe program funds research and innovation activities in transportation, including batteries, clean hydrogen, low-carbon steel manufacturing, the cyclical bio-based sector and the built environment. We therefore believe that the proposed blanket Restriction of all PFAS for all uses, including uses that are critical to the European Green Deal, would essentially hamper the achievement of European Green Deal objectives.

2. The proposed Restriction would significantly and disproportionately hamper international trade

If the proposed Restriction is implemented as currently announced, trade in essential goods in which PFAS are used would be considerably restricted and supply chains around the world would be severely disrupted.
In our view, even if alternative substances are currently being developed, these would need to go through repeated demonstrations and evaluations and therefore they would take considerable time before they can be implemented. Moreover, for substances for which no alternatives have been identified yet, research and development will have to be promoted through trial and error in the future, and even a 12 year grace period may not be sufficient to confirm their availability.

The serious and disproportionate negative effects of the proposed Restriction on international trade could also constitute a violation of the proportionality principle as enshrined in Article 68(1) REACH. In particular:

The proposed Restriction is disproportionate, contrary to Article 68 (1) REACH.

Article 68(1) REACH requires that any restriction decision shall take into account "the socio-economic impact of the restriction, including the availability of alternatives". That socio-economic impact may, among others, include, in accordance with Annex XV, i) the impact of the restriction on the industry (e.g. manufacturers and importers) and on all other actors in the supply chain in terms of commercial consequences, including impact on investment, operating costs and innovation; ii) the wider implications on trade, competition and economic development; iii) alternative risk management measurements that could meet the aim of the proposed restriction and iv) the availability of suitable and feasible alternatives.

The proposed Restriction does not appropriately consider those elements of the socio-economic impact and fails to balance the negative impact on international trade and the Industry with the potential benefits of the proposed measure. It rather proposes a blanket restriction of all PFAS substances for all uses (beyond some transitional periods for specific uses/applications) that goes well beyond what is necessary to achieve the legitimate objectives it pursues, and is not the least onerous measure to control the potential risks posed by certain PFAS.

In particular, the Proposed Restriction fails to conduct a substantial assessment of the "availability of alternatives" including: i) where alternatives have been identified, these must be compared as to their risks and benefits to the substances proposed to be restricted and ii) where alternatives are not yet available, the risks of the continued use of the substances proposed to be restricted should be compared with the socio-economic consequences of them no longer being available and of the lack of available alternatives.

In light of the above, we request that the EU limits the scope of the restriction to the extent necessary to achieve the objectives that contribute to the social economy of the EU. In that regard, we also request that if the restriction remains as it is, that the EU considers a "review clause" that would enable the extension of the transitional periods in case suitable alternatives have not been developed by the given review date.

3. The proposed Restriction restricts all PFAS as a single group

In following this grouping approach, the proposed PFAS Restriction would restrict PFAS that have not been risk-assessed and for which an unacceptable risk has not been demonstrated, in breach of Article 68(1) REACH.

Article 68(1) REACH provides that substance(s) can be restricted only if they pose an unacceptable risk to human health or the environment. This unacceptable risk must be positively demonstrated by conducting a risk assessment that follows the conditions of Annex XV to REACH (and by cross-reference of Annex I and Annex XIII). Such risk assessment comprises hazard identification and characterisation, exposure assessment and risk characterisation.

By grouping all various PFAS substances together and restricting them as a single class, the proposed PFAS Restriction Proposal would restrict numerous PFAS substances that have not been risk-assessed and for which no unacceptable risk has been demonstrated, in breach of Article 68(1) REACH.

More specifically, the scope of the proposed PFAS Restriction is based on the OECD definition of PFAS. That definition is only based on chemical structure and does not take into account hazardous properties or risks of PFAS, as the proposed Restriction itself acknowledges (p. 19). As a result, it covers approximately 10,000 substances with very diverse physical, chemical and biological properties and behaviour. That broad definition does not take into account the specific, distinct properties of different individual PFAS or PFAS subgroups and is therefore not suitable for regulatory risk management purposes. OECD itself acknowledges that this definition "does not conclude that all PFASs have the same properties uses, exposures and risks" and that it can only serve a starting and reference point as it "may be viewed as too broad" (OECD, 2021, Reconciling Terminology of the Universe of Per- and Polyfluoroalkyl Substances: Recommendations and Practical Guidance).

In particular, the very broad scope of proposed Restriction –which is based on the OECD PFAS definition- does not enable a legally and scientifically sound risk assessment. By grouping all PFAS together in a single group for risk assessment, the proposed Restriction fails to identify and consider the specific, distinct properties of each individual PFAS or PFAS subgroup and, in turn, to assess and characterise the hazards and risks related to those properties in order to demonstrate that they pose an unacceptable risk to human health or the environment.

It rather restricts all PFAS substances on the assumption that they all share a very persistent property as their "key hazardous property" that ”triggers equivalent hazards and risks”(p.21-22). However, (very) persistence is not per se a hazardous property nor does it indicate a risk on its own. Persistence on its own is also not sufficient to consider PFAS as giving an "equivalent level of concern" to PBTs/vPvBs or to characterise an "unacceptable risk" within the meaning of Article 68(1) REACH and justify a restriction. It is for those reasons that persistence is only regulated in combination with other properties in the REACH and CLP

Regulation (e.g. together with bioaccumulation, toxicity or -under the new hazard classes introduced to the CLP Regulation- mobility), and not alone.

Beyond PFAS' purported very persistent property, the proposed Restriction does not identify any other hazardous properties that are common to all PFAS. It only refers to some additional properties that amplify the "overall concern" for some -not all- PFAS. Indeed, the Proposal contains evidence that concerns only certain sub-sets of PFAS (mostly some long-chain PFAS) and lacks data on other PFAS substances/subgroups and an adequate justification as to why the conclusions for certain PFAS would be applicable to all PFAS covered by the proposed Restriction (read-across).

For example, the proposed Restriction acknowledges that "for the majority of PFAS no, or insufficient, data on bioaccumulation behaviour are available" and therefore that the "data on the bioaccumulation potential of PFAS [..] are not sufficient to substantiate bioaccumulation in the environment for all PFAS" (p.28). With respect to ecotoxicity, it mentions that "the large number of different substances with heterogenous properties […] in the group of PFAS makes the assessment of their ecotoxicity very complex"(p.28). It then concludes that the bioaccumulation potential and (eco)toxicity is expected to vary among PFAS due to their "high diversity" and that "no overall conclusion on B/Vb and T criteria was derived for each PFAS substance/ (sub-) group" (p. 47).

In the absence of (sufficient) evidence, the proposed Restriction fails to conduct a risk assessment, comprising a hazard assessment and characterisation, exposure assessment and risk characterisation, to demonstrate an unacceptable risk posed by all PFAS substances proposed to be restricted. For example, in some applications, PFAS may be used in enclosed spaces, where exposure to the environment is extremely limited and the risk to human health and environmental conservation is even less. It is also possible that by not characterising the specific risk(s) each individual PFAS/PFAS subgroup poses that the proposed Restriction would lead to the replacement of those PFAS with non-PFAS alternatives that could be potentially more harmful to human health and the environment (regrettable substitution).

Even if certain PFAS would be demonstrated to pose an "unacceptable risk to human health or the environment" within the meaning of Article 68(1) REACH, this cannot lead to the conclusion that all PFAS pose such an unacceptable risk, without considering their varying properties and behavior.

4. The proposed Restriction could not be lawfully based on the precautionary principle

Article 68(1) REACH requires positive demonstration that there "is" an unacceptable risk. It is therefore not intended as a tool to address scientific uncertainties, as it is the case with the precautionary principle. Therefore, the proposed Restriction that is largely based on scientific uncertainties (e.g. "lack of toxicological data for the vast majority of [PFAS]"(p.32); " for most PFASs there are insufficient data to adequately assess their effects on human health and the environment" (p.13); "for the majority of PFASs no, or insufficient, data on bioaccumulation behaviour are available" (p. 28)) would not meet the requirement of Article 68(1) REACH to demonstrate an unacceptable risk.

In the alternative, even if the proposed Restriction applies the precautionary principle (although it makes no mention of it), it must had nevertheless met the conditions of EU case law, as summarised in the Commission Communication on the precautionary principle, which it failed to do.

In particular:

According to settled EU case law (e.g. T-584/13), the precautionary principle is “a general principle of EU law requiring the authorities […] to take appropriate measures to prevent specific potential risks to public health, safety and the environment […]”. It should be used where “there is scientific uncertainty as to existence or extent of risks to human health or the environment […].” While the risk assessment in the context of the precautionary principle is “not required to provide […] conclusive scientific evidence of the reality of the risk and the seriousness of the potential adverse effects were that risk to become a reality”, “a preventive measure cannot properly be based on a purely hypothetical approach to the risk, founded on mere conjecture which has not been scientifically verified” (our emphasis).

However, the proposed Restriction lacks evidence of effects, and especially, of effects that are adverse. Indeed, as the Proposal itself acknowledges “for most PFAS there are insufficient data to adequately assess their effects on human health and the environment” (p. 13) and that “if releases are not minimised, humans and other organisms will be exposed to progressively increasing amounts of PFASs until such levels are reached where effects are likely” (p. 50). In the same vein, the Proposal also mentions that “[i]t is more likely that for the vast majority of these substances, no study data are available to serve as a basis for classification. In the absence of evidence to the contrary, it can therefore be assumed that some of the less well-studied PFAAs and PFAA precursors also exhibit one or more of the properties of concern.”(p.30).

Moreover, the persistence and accumulation of PFAS in the environment that the proposed Restriction mainly relies on, cannot be construed as adverse effects per se.The Proposal is therefore based merely on unsubstantiated assumptions.

In addition, the proposed Restriction fails to meet the following conditions for the implementation of the precautionary principle set out in the Commission Communication on the Precautionary Principle (Communication from the Commission on the precautionary principle. Brussels, 2.2.2000 COM(2000) 1 final).

- Before the adoption of a precautionary measure, there must be first a scientific risk assessment, comprising four steps, namely hazard identification, hazard characterisation, appraisal of exposure and risk characterisation. In our opinion one could demonstrate that these four steps have not been followed in the PFAS Restriction Proposal. The alleged hazards of the PFAS have not been established and, likewise, there is little on the actual exposure to PFAS. These elements have rather been postulated on unsubstantiated assumptions. In the absence of reliable information on hazard and exposure, there is no basis on which to characterise the risk, and therefore to conduct the required scientific risk assessment for the application of the precautionary principle.
- The precautionary measure must be proportionate, non-discriminatory and consistent with similar measures, based on examination of the potential benefits and costs. In our opinion, the proposed PFAS restriction could be demonstrated to be disproportionate and not the least restrictive measure that can be taken to address any PFAS-related concerns because i) it restricts the entire class of PFAS for all applications on the basis of mainly a “persistency concern”; ii) it does not sufficiently assess the risk and suitability of allegedly available alternatives, and iii) it does not (adequately) assess the socio-economic impact of such broad restriction against the alleged “significant benefits” of the restriction.
- The Proposal must identify the measures that need to be taken in order to clarify the uncertainties that could justify precautionary measures. In particular, “measures based on the precautionary principle should be subject to […] to review in the light of new scientific data.” In that respect, the Proposal does not propose measures that could be taken to resolve the uncertainties it identifies – it rather proposes a total, blanket ban of all PFAS for all applications (beyond some transitional periods for some applications).

5. The proposed Restriction would restrict substances without listing them contrary to Article 68(1) REACH

Article 68(1) provides that substances that pose an unacceptable risk to human health or the environment could be the subject of a restriction. Article 68(1) restriction should therefore identify the substances proposed to be restricted. Annex XV, Section 3 of REACH also specifies that the restriction "shall include the identity of the substance […]". Such identify should be chemical specific, including name, identification numbers, molecular and structural

formulas, etc. Indeed, REACH defines a "substance" as "a chemical element and its compounds" (Article 3(1) REACH). This is also clearly reflected in the European Chemicals Agency (ECHA) Guidance for the preparation of an Annex XV dossier (p. 108) that specifies that the restriction proposal must provide "details on the identity of the substance (name, CAS, EC number, registration number (if available), molecular formula, structural formula, purity and impurities)".

In light of the above, the proposed Restriction fails to adequately identify and list the specific chemical substances proposed to be restricted. Instead, it prohibits the manufacturing, use or placing on the market of any substance "that contains at least one fully fluorinated methyl (CF3-) or methylene (-CF2-) carbon atom, without any H/Cl/Br/I attached to it" (p.4). It does not provide the names or identification numbers of the specific substances that are covered by this broad definition, as required.

（2）Exclusion by PFAS Sub-category(substance)

As mentioned in (1), a class of compounds (PFAS sub-category) having widely different properties, such as fluoropolymers and fluorinated gases, are all grouped as PFAS and subject to restrictions. On page 16 of the report, citing the OECD report, PFAS are sub-categorised into 4 major categories and 30 middle categories. B.3 Classification and labeling and B.4 Environmental fate properties in the Annex B report and are evaluated based on these sub-categories, respectively, and we believe that risk can be more appropriately assessed by sub-categorising rather than grouping as PFAS.

For example, fluoropolymers are thermally, biologically, and chemically stable, barely soluble in water, immobile, insoluble (Water, Octanol, etc.), and too large to migrate to cell membranes, so they are not incorporated into the body and are considered low concern from a human and environmental health perspective[1,2]. The findings demonstrate that fluoropolymers are a distinct group from PFOA and PFOS and should not be combined with them for hazard assessment or regulatory purposes. Fluoropolymers are the only materials that simultaneously possess heat resistance, weather resistance, chemical resistance, water repellency, lubricity, and unique optical/electrical properties, and they have become indispensable materials in many fields, including the energy field (Fuel cells and lithium-ion batteries), semiconductor field (Clean members, etching gas), electrical and electronic communications field (Wire cladding and liquid crystal materials), transportation field (Cars, airplanes, railroads), and medical field (Catheters, protective clothing). It is necessary to carefully re-examine whether the uniform regulations for PFAS are appropriate in light of the chemical hazards and risks of the substances in question. In particular, fluoropolymers

should be excluded from the current regulations because they are highly stable materials and have no concerns about bioconcentration or toxicological effects.

Fluorinated gas is a highly safe compound in terms of toxicity and combustibility, and it is used in many applications in terms of efficiency and cost. In addition, fluorinated gas itself is not persistent in the persistent properties proposed in the PFAS restriction proposal. In addition, trifluoroacetic acid, which is a degradable product of fluorinated gas itself and is a concern in the proposed restriction, has also been shown to pose a low risk of toxicity to living organisms and human bodies in the reports of the Environment Agency of Germany and Norway, who actually submitted this restriction proposal[3,4]. These results indicate that fluorinated gas should not be considered for regulation as a group with PFOA and PFOS.

In addition, the reduction of fluorinated gas usage is being considered in the F-gas regulations, and from the standpoint of dual regulations, we do not believe that it should be considered in the PFAS regulations.

Reference:

1: Barbara H et al., Integrated Environmental Assessment and Management, Vol14(3), p316–334.
https://setac.onlinelibrary.wiley.com/doi/full/10.1002/ieam.4035
2: Stephen K et al, Integrated Environmental Assessment and Management, Vol19(2), p326–354
https://setac.onlinelibrary.wiley.com/doi/10.1002/ieam.4646
3: German Environment Agency, Reducing chemical input into water bodies – trifluoroacetate (TFA) as a persistent and mobile substance from many sources, 2021
4: Norwegian Environment Agency, Study on environmental and health effects of HFO refrigerants, 2017