Memorandum

Date	22.03.2023
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To	European Chemicals Agency

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Az. 59/23, MA, D3-23

Legal Observations

Proposal for a restriction of Per- and polyfluoroalkyl substances (PFAS) according to Regulation (EC) No. 1907/2006 (REACH)

submitted by

- BAuA, Federal Institute for Occupational Safety and Health
- Bureau REACH, National Institute for Public Health and the Environment (RIVM)
- Swedish Chemicals Agency (KEMI)
- Norwegian Environment Agency
- The Danish Environmental Protection Agency

Version 2.0
Date: 22.03.2023

prepared for and on behalf of

Gujarat Fluorochemicals GmbH

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Amtsgericht Augsburg · HRB 34009

Zugelassen bei der
Rechtsanwaltskammer für den
Oberlandesgerichtsbezirk München

USt.-ID: DE325991634

Bankverbindung
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A. Executive Summary

(1) The legal basis for the Proposal is Article 68(1) REACH. This provision requires, that an unacceptable risk to human health or the environment, arising from the manufacture, use or placing on the market of the substance(s) within the intended scope is demonstrated. The Proposal substantially deviates from applicable legal prerequisites and principles. It is, therefore, flawed from a factual, technical and legal perspective as far as Fluoropolymers are included in the scope.

(2) The scope of the Proposal, in essence, is based on the OECD definition of PFAS established in 2021. This definition also includes Fluoropolymers.

(3) Insofar, however, the Proposal does not meet the requirements for a grouping approach under REACH. This would require that all substances within the scope share the key property in combination with the exposure that causes the risk leading to the proposal of a restriction. The Proposal is based on the assumption that all PFAS qualify as persistent and do have other hazard properties in addition to their persistence. The Proposal, however, lacks a mandatory risk assessment to demonstrate that Fluoropolymers share the same or similar hazard properties with other PFAS. In particular it needs to be noted that Fluoropolymers do not meet the criteria for being bioaccumulative, mobile or toxic. It follows already from scientific evidence that Fluoropolymers should not be included in the grouping approach.

(4) Furthermore, the Proposal fails to demonstrate that there is an unacceptable risk to human health or the environment with respect to Fluoropolymers. Insofar, any proposal for a restriction needs to be based on a hazard assessment. Mere reference to the OECD PFAS definition is not sufficient as the definition is not established on the assessment whether a compound is harmful or not. Moreover, the assumption that all PFAS qualify as persistent is not sufficient, as persistence as such does not even qualify as a hazard criterion, which is already acknowledged by the Proposal.

(5) Restricting Fluoropolymers as supported by the Proposal does also not align with the precautionary principle. A correct application of that principle presupposes identification of the potentially negative consequences of the proposed use of Fluoropolymers as well as a comprehensive assessment of the associated risks based on the most reliable scientific data available and the most recent results of international research. The Proposal lacks sufficient evidence in this regard and is based on a mere hypothesis rather than on a scientifically substantiated risk assessment. This specifically holds true for Fluoropolymers, for which no respective hazard and, consequently, no corresponding risk can be identified.

(6) Moreover, the Proposal breaches the principle of proportionality with respect to Fluoropolymers. Due to the fact that any emission in connection with the entire life-cycle of Fluoropolymers from manufacturing to use until the end-of-life stages are to be consid-

ered *de minimis* if fluorinated polymerisation aids are restricted, a restriction of Fluoropolymers as such would not be necessary at all against the background of the principle of proportionality.

(7) In addition, the Dossiers Submitters erroneously have chosen the restriction procedure under REACH for an intended approach which, in fact, is structured with significant similarity to an authorisation proceeding. The contemplated process to accept potential applications and to decide on potential for exemptions or derogations basically establishes a requirement for stakeholders to provide any and all evidence to substantiate a corresponding request within a unreasonable short time period and, therefore, shifts the burden of proof to stakeholders contrary to the legal perquisites defined in Article 68 REACH.

(8) All in all, and irrespective further concerns on the Proposal demonstrating infringements of e.g. the principle of good administrative behaviour or the right to be heard and the right to comment, Fluoropolymers manufactured without the use of fluorinated polymerisation aids should be exempted from the scope of the Proposal. Without a corresponding exemption or derogation significant market distortion are to be expected as critical products, technologies or applications will no longer be available if removed from the market due to the contemplated restriction.

B. Starting Point

I. Gujarat Fluorochemicals Limited

(9) Gujarat Fluorochemicals Limited (hereinafter referred to as "**GFL**") is an Indian Chemicals Company with over 30 years of expertise in Fluorine Chemistry. GFL holds domain expertise in Fluoropolymers, Fluorospecialities, Refrigerants and Chemicals, catering to the material requirements of modern world. GFL leverages its competencies in Fluorine-based products through product innovation and customer partnerships in diverse end-use markets. Impacting mobility, telecommunications, healthcare and architecture, GFL constantly challenges itself to find solutions to some of the most demanding applications.

(10) GFL is committed to sustainable operations and corporate social responsibilities. Focus on clean processes, continuous development of new applications, customised solutions and consistent services make GFL one of the reliable strategic partners for our clientele globally.

II. Background

(11) GFL commissioned Produktkanzlei – Ahlhaus Handorn Niermeier Schucht Rechtsanwaltsgesellschaft mbH (hereinafter referred to as „**Produktkanzlei**") to assess the proposal for a restriction of Per- and polyfluoroalkyl substances (individual substances and/or the group of substances hereinafter referred to "**PFAS**", unless explicitly specified otherwise) according to Regulation (EC) No. 1907/2006 (hereinafter referred to as "**REACH**") as submitted by the German Federal Institute for Occupational Safety and Health (hereinafter referred to as "**BAuA**"), the Dutch Bureau REACH, National Institute for Public Health and the Environment (hereinafter referred to as "**RIVM**"), the Swedish Chemicals Agency (hereinafter referred to as "**KEMI**"), the Norwegian Environment Agency and the Danish Environmental Protection Agency (hereinafter jointly referred to as the "**Dossier Submitters**").

(12) This memorandum summarizes the findings of the legal assessment with a special focus on general legal concerns as well as legal implications due to the fact that the intended restriction shall, in general, also cover Fluoropolymers.

(13) The legal assessment is based on the aforementioned proposal as submitted on 13 January 2023 and initially published by the European Chemicals Agency (hereinafter referred to as "**ECHA**") on 7 February 2023. As the Dossier Submitters provided an updated version of the proposal, i.e. Version 2.0, as of 22.03.2023 (hereinafter referred to as "**Proposal**"), only this version is considered.

(14) Following the prerequisite according to Article 69(6) REACH, ECHA has started the public consultation on the Proposal on 22 March 2023. Submissions can be made until 25 September 2023.

(15) This legal assessment of the Proposal is drafted to supplement a broader submission of GFL within the public consultation. Produktkanzlei explicitly confirms that GFL is entitled to use this memorandum for this purpose.

(16) We respectfully request to consider this submission in connection with the further proceeding to avoid further procedural flaws. We understand that the process to develop opinions at level of the Committee for Risk Assessment ("**RAC**") and the Committee for Socio-Economic Analysis ("**SEAC**") will be initiated already prior to the end of the period granted for submissions in the public consultation. While we further understand that the time period for opinion development as established in Articles 70, 71(1) REACH does require immediate action at committee level, we submit that any and all submissions need to be taken into consideration. The mere fact that opinion development has been initiated prior to the end of the consultation period should not result in a scenario that substantial submissions are not sufficiently considered. Therefore, we respectfully request ECHA, RAC, SEAC and the Dossier Submitters to consider the concerns raised with this submission and the further arguments as brought forward and supported by the broader submission of GFL to avoid procedural shortcomings which might give rise to further legal concerns.

C. Legal Assessment

(17) From a legal perspective, it needs to be assessed whether the Proposal meets the applicable requirements for restrictions according to Title VIII of REACH from a procedural, scientific and legal perspective taking into account the scope of the Proposal as well as the underlying justification. Insofar, the following submissions need to be made on the Proposal.

I. Fluoropolymers in the restriction proposal

(18) In general, we understand that Fluoropolymers qualify as PFAS within the (new) OECD definition on PFAS and would, therefore, be within the scope of a restriction according to the Proposal.

(19) This is already acknowledged in the Proposal insofar as Fluoropolymers are explicitly addressed, including but not limited by means of specific derogations for Fluoropolymers and the related use of polymerisation aids as set out in Nos. 5a), 6, 7 and 8 (cf. Proposal, p. 4 et seqq.).

(20) This notwithstanding, the proposal also underpins the fact that the Dossier Submitters consider Fluoropolymers to be a distinct group of PFAS. This view is supported by many sections of the Proposal in which Fluoropolymers are discussed separately, which indicates their independent and distinct position within the group of PFAS.

(21) The proposed restriction following Restriction Option 2 (cf. Proposal, p. 4) contains a specific series of time-limited derogations for certain uses of Fluoropolymers in Column 2, No. 6. According thereto, the restriction shall not apply to Fluoropolymers and perfluoropolyethers for the use in food contact materials for the purpose of industrial and professional food and feed production until 6.5 years after entry into force ("EiF"); implantable medical devices (not including meshes, wound treatment products, tubes and catheters) until 13.5 years after EiF; tubes and catheters in medical devices until 13.5 years after EiF; coatings of Metered Dose Inhalers (MDIs) until 13.5 years after EiF; proton-exchange membrane (PEM) fuel cells until 6.5 years after EiF and fluoropolymer applications in petroleum and mining industry until 13.5 years after EiF.

(22) Furthermore, according to the proposed entry in Column 2, No. 8, importers and downstream users of Fluoropolymers and perfluoropolyethers making use of any of the derogations shall establish a site-specific management plan which shall include information on the identity of the substances and the products they are used in, a justification for the use and details on the conditions of use and safe disposal. Additionally, the management plan shall be reviewed annually and kept available for inspection by enforcement authorities upon request.

(23) Of the many other sections in the proposal where specific reference is made to Fluoropolymers, the most important one is, that Fluoropolymers are the only group of PFAS

for which a separate assessment is provided within the environmental hazard assessment set out in Annex B to the Proposal (cf. Proposal, Annex B, p. 219 et seqq.).

II. Objections against the inclusion of Fluoropolymers

(24) Even if one were to assume that the Proposal and the underlying aims and purposes are reasonable, the Proposal fails to demonstrate that the inclusion of Fluoropolymers would meet the requirements according to Article 68(1) REACH and general principles of law which need to be adhered to in connection with the introduction of a restriction under REACH.

(25) First of all, it needs to be noted that Article 68(1) REACH establishes the prerequisites for a restriction under REACH as follows:

> *"When there is an unacceptable risk to human health or the environment, arising from the manufacture, use or placing on the market of substances, which needs to be addressed on a Community-wide basis, Annex XVII shall be amended in accordance with the procedure referred to in Article 133(4) by adopting new restrictions, or amending current restrictions in Annex XVII, for the manufacture, use or placing on the market of substances on their own, in mixtures or in articles, pursuant to the procedure set out in Articles 69 to 73. Any such decision shall take into account the socio-economic impact of the restriction, including the availability of alternatives."*

(26) The Proposal, however, deviates from these requirements by broadly referring to the OECD definition of PFAS, including Fluoropolymers, without providing sufficient scientific evidence that there is an unacceptable risk to human health or the environment resulting from the manufacturing or use of Fluoropolymers.

1. Failure to meet the prerequisites established in Article 68 REACH: hazard to human health / environment

(27) The proposal fails to meet the requirements arising from the wording of Article 68(1) REACH with respect to Fluoropolymers. The wording requires that there is an unacceptable risk to human health or the environment, arising from the manufacture, use or placing on the market of substances, which needs to be addressed on a community-wide basis. The basic requirement is therefore that there is a hazard to human health or a hazard to the environment. Only in a subsequent step it has to be examined whether, due to exposure, a risk arises as a result of this. However, the dossier is not able to prove that Fluoropolymers pose a hazard to health or environment at all.

a) Failure to conduct proper hazard assessment

(28) The Proposal is flawed from the very beginning since there is no hazard assessment conducted as required by REACH. As a mandatory prerequisite to adopt a restriction under REACH, Article 68(1) REACH requires that there is an unacceptable risk to human

health or the environment, arising from the manufacture, use or placing on the market of a substance, which needs to be addressed on a community-wide basis. The basic requirement is therefore that the substance under scrutiny has been identified to pose unacceptable risk to human health or the environment. Following the fundamental principles enshrined in the REACH Regulation, any corresponding risk assessment needs to be based on an assessment of the hazard properties of the substances involved.

(29) If a corresponding risk assessment would have been initiated in accordance with applicable requirements, it would have been already obvious from the relevant results that Fluoropolymers should not be included in the scope of the Proposal.

aa) Hazard assessment as a mandatory starting point for restriction proposals

(30) It follows already from the legal prerequisites that a profound hazard assessment is a mandatory starting point for any restriction proposal under REACH. This fundamental principle already follows from Article 69(4) of REACH, as any dossier submitter needs to refer to any corresponding dossier, chemical safety report or risk assessment established under REACH for the substance at issue in the restriction proposal. Any such dossier, however, mandatorily contains details on the hazard properties of the substances under scrutiny.

(31) We submit in this context, that the term dossier refers to any dossier prepared under REACH as Article 69(4) REACH does not limit its scope to certain types of dossiers. Therefore, the Dossier Submitters were required to take into consideration corresponding registration dossiers or any available dossiers already established in accordance with Annex XV for substances within the scope of the proposed restriction. It should be noted, however, that for both types of dossiers, the identification and assessment of hazard properties is essential and, moreover, a mandatory requirement.

(32) First, this holds true for registration dossiers as hazard properties according to Regulation (EC) No. 1272/2008 ("**CLP**") need to be indicated for any substance subject to registration requirements. This follows directly from Annex V Section 4 to REACH, but also hazard properties as defined in Annex XIII to REACH have to be assessed in connection with standard information requirements applicable to the registration of substances under REACH according to Annex VII.

(33) Second, also any dossier established in accordance with Annex XV to REACH needs to comprise an assessment of hazard properties.

(34) This holds true for dossiers established to identify potential substances of very high concern. The details for such dossiers are outlined in Annex XV Section 2 to REACH. Corresponding dossiers need to demonstrate that the prerequisites as set out in Article 57 REACH read in conjunction with Article 59 REACH are met. Insofar, such dossiers only relate to hazard properties of substances from the outset. In addition, Article 58(1)(b)

REACH emphasizes that properties as referred to in Article 57 REACH are to be considered as "intrinsic properties". Insofar, Article 58(1)(b) REACH follows the general principle as set forth in the CLP Regulation that hazard classification is to be determined on basis of the intrinsic properties of a substance (cf. Judgment of the General Court of 23 November 2022, Cases T-279/20 and T-288/20). The explicit reference to intrinsic properties underpins the fact that the identification of substances of very high concern is based on an assessment of the hazard properties of a substance.

(35) We further submit, that the same holds true for dossiers according to Annex XV aiming at a proposal to establish a restriction under REACH as referred to in Annex XV Section 3 to REACH. This specific section states that the corresponding dossier needs to contain information on hazard and risk, whereby the risks to be addressed with the restriction shall be described based on an assessment of the hazard and risks according to the relevant parts of Annex I to REACH and shall be documented in the format set out in Part B of that Annex for the Chemical Safety Report. Therefore, also restriction proposals, as in the case at hand on PFAS, need to contain a sufficient assessment of hazard properties as a basis for the identification and further assessment of related risks.

(36) As far as Annex XV Section 3 to REACH refers to chemical safety reports according to Annex I to REACH, it should be taken into account, that these require, as a starting point, the consideration of information related to the hazards of a substance. The sub-paragraph following Section 0.5 explicitly states that "the information to be considered includes information related to the hazards of the substance". In addition, Section 0.6.1. of Annex I to REACH stipulates that the hazard assessment is the first step to perform a chemical safety assessment.

(37) Moreover, Section 0.6.3 in Annex I to REACH clarifies that any risk characterization shall be based on an exposure assessment which need to relate to the identified hazard properties of the substance under scrutiny.

(38) A hazard assessment is, therefore, a mandatory starting point for each and every proposal of a restriction under REACH. Only on that basis and in a subsequent step, it needs to be assessed if and to what extent a risk to human health or the environment arises from the corresponding hazards and relevant exposures. And only if the identified risk turns out to be unacceptable, a restriction according to Article 68(1) REACH is warranted (cf. Guidance for the preparation of an Annex XV dossier for restrictions, figure 4, p. 32).

bb) No alternative approach available

(39) We further submit, that a hazard assessment as an initial mandatory step cannot be replaced or circumvented by any other approach. Article 68(1) REACH read in conjunction with Annex XV to REACH and the corresponding guidance does not provide for any deviating option. This even holds true with respect to more generic options for potential restrictions as provided for in Article 68(2) REACH as such an approach mandatorily requires the identification of applicable hazard properties of the respective substances.

(40) It should also be noted that Article 68 REACH does not contain any provision similar to Article 57(f) REACH, so that a restriction proposal can be justified on basis of some sort of an "equivalent level of concern". While already Article 57(f) REACH would require a hazard assessment as set out in Section 2 of Annex XV to REACH, it goes without saying that Article 68 REACH does not contain any language that could support the view that a hazard assessment could be negligible.

(41) Only if risks derived from hazard properties of a substance and related exposure can be established and proven to meet the further criteria laid down in Article 68(1) REACH, a restriction proposal on basis of a dossier according to Annex XV to REACH would meet applicable legal requirements. Contrary to the underlying assumption referred to in the Proposal, it is not sufficient to bring forward merely general assumptions about a substance being hazardous or giving rise to a specific or general concerns.

cc) No hazard property beyond persistence identified for Fluoropolymers

(42) According to the Proposal, persistence is the key property common to the thousands of substances defined as "PFAS" under the Proposal (cf. Proposal, p. 22). Apart from persistence, the Proposal identifies additional concerns that differ depending on the type of PFAS, including, among others, Long-Range Transport Potential ("**LRTP**"), Mobility, Accumulation in plants, Bioaccumulation, Ecotoxicty, Endocrine Activity / Endocrine Disruption and effects on human health (p. 22). However, data do not exist for each and every of the thousands of substances that fall within the scope of the Proposal as established on basis of the respective "PFAS" definition, including Fluoropolymers. Without corresponding data, the Proposal lacks sufficient evidence to substantiate that one or more of additional concerns, i.e. hazard properties, apply to the substances within the scope of the contemplated restriction. Also other scientific methods to extrapolate such hazard properties are not provided in the Proposal. Instead, the Dossier Submitters seem to take the position that a sufficient risk within the meaning of Article 68(1) REACH can legally and scientifically be based on the (presumed) persistence of all PFAS that remain within the scope, and the additional assumption that any PFAS is likely to have also other hazard properties, although these are only substantiated for a limited number of the thousands of substances defined as "PFAS".

(43) This approach, however, does not meet the prerequisites of Article 68(1) REACH and it cannot be based on any other provision of the REACH Regulation. Consequently, the Proposal fails to provide evidence for a sufficient hazard assessment as required by the REACH Regulation. This specifically holds true with respect to Fluoropolymers, as no hazard properties can be identified beyond the persistence.

b) Hazard to human health

(44) The proposal itself already states on a general level (cf. Proposal, p. 29) that while there is a vast amount of literature published on the health effects of PFAS, most of the liter-

ature relates to the PFAA arrowheads PFCAs and PFSAs, especially PFOA and PFOS. Furthermore, according to the proposal, other PFAS (like Fluoropolymers) have been less well-studied. Accordingly, the human health hazard assessment in Annex B of the dossier states in its first two sentences, that the majority of available data on human health effects address the toxicity of PFAAs (mainly PFCAs and PFSAs; in particular PFOA and PFOS), while less or no data are available for other PFAS groups and that for the vast majority of PFAS (estimated >99%), no data on repeated-dose toxicity, carcinogenicity, or reproductive toxicity is available (Annex B, p. 141).

(45) The proposal admits (cf. Proposal, p. 29) that some precursors to PFAAs may be of less direct concern with regard to human health effects and only indirectly add to the concern (due to degradation). In addition, the proposal states with regard to PFAAs that data available for less well-studied PFAA arrowheads and some PFAA precursors indicate that these PFAS can have similar effects as the well-studied ones mentioned above (cf. Proposal, p. 30).

(46) In this respect, the proposal already shows on the summary level that there is no scientific evidence for the existence of a risk to human health for all substances covered by the restriction proposal. In particular, there is no such evidence regarding Fluoropolymers, which, according to the Proposal, have been less researched.

(47) In particular, the dossier explicitly states with regard to polymeric PFAS, and accordingly for Fluoropolymers, that properties of the substances can vary considerably and that a clear assignment of the substance to health effects is complicated, because unique identifiers are often not available (cf. Proposal, p. 31). Additionally, the proposal states that the end-of-life fate of the polymers is uncertain (cf. Proposal, p. 31). According to the dossier, only a few studies with toxicological information are available for this diverse group of oligomeric and polymeric PFAS. Most available toxicological studies of oligomeric/polymeric PFAS investigated oligomeric PCTFE oils and pure PCTFE oligomers (cf. Proposal, p. 31).

(48) Hence, there is no significant proof or evidence that polymers and in particular Fluoropolymers pose a risk to human health equal or similar to other PFAS within the scope of the proposed restriction or any risk at all. To the contrary, scientific articles on Fluoropolymers demonstrate that fluoropolymers satisfy widely accepted assessment criteria to be considered as "polymers of low concern" ("**PLC**"; e.g. *Henry* et al., Integrated Environmental Assessment and Management, 2018, p. 316 et seqq., DOI: 10.1002/ieam.4035, available at https://setac.onlinelibrary.wiley.com/doi/full/10.1002/ieam.4035; *Korzeniowski* et al., Integrated Environmental Assessment, 2022, p. 326 et seqq., DOI:10.1002/ieam.4646, available at setac.onlinelibrary.wiley.com/doi/10.1002/ieam.4646). Accordingly, the dossier sees no clarity on effects after repeated exposure of polymeric PFAS based on available data (cf. Proposal, p. 31). In the end, the proposal concludes that polymeric PFAS contribute to the overall risks of non-polymeric

PFAS because, according to the Proposal, they "may generate and/or release non-polymeric PFAS", in particular at the end-of-life. In itself, this is not sufficient to substantiate a hazard to human health, since the proposal indicates no certainty that non-polymeric PFAS are generated or released at any point. Moreover, the proposal itself states that the end-of-life fate of the polymers is uncertain (see above), therefore it is contradictory when it is stated a few sentences later that there "may" be a release of non-polymeric PFAS in particular at the end-of-life.

(49) In this respect, we reiterate that available data demonstrates that Fluoropolymers meet the criteria for PLC (*Henry* et al., loc. cit.; *Korzeniowski* et al, loc. cit.). Although the Proposal takes note of the corresponding publication (*Henry* et al., loc. cit; cf. Proposal, p. 46), the respective findings are only discussed in connection with bioavailability of Fluoropolymers. The Dossier Submitters, however, should have taken note of the fact that available fluoropolymer toxicity data (including available human clinical data) demonstrate that Fluoropolymers do not pose a risk to human health equal or similar to other PFAS within the scope. Moreover, an analysis of Annex B to the Proposal also shows that the scientific data with regard to the hazard of Fluoropolymers to human health is very weak and does not establish sufficient scientific evidence to justify the inclusion of Fluoropolymers in the scope of the Proposal. As shown below, the evidence with regard to the main category of polymers is not given:

- Regarding toxicokinetics/ADME, the proposal states that no studies are available on toxicokinetics of polymeric PFAS (Annex B.5.1.2, p. 154)

- With regard to liver effects in experimental animals, the proposal sums up that there are only indications that oligomeric PFAS (not Fluoropolymers) can cause adverse liver effects and that clarity on liver effects of oligomeric/polymeric PFAS cannot be given on the basis of available data (Annex B B.5.2.1.1, p. 159).

- As for kidney effects in experimental animals, the proposal sums up that there are only indications that low molecular weight oligomeric/polymeric PFAS can cause kidney effects but clarity on kidney effects of oligomeric/polymeric PFAS cannot be given on the basis of available data (Annex B.5.2.1.3, p. 163) Moreover, it is not considered that Fluoropolymers have negligible residual oligomer content.

- For oligomeric/polymeric PFAS, no studies observing thyroid parameters are known (Annex B.5.2.1.4, p. 164).

- Regarding immune effects in experimental animals, the proposal concludes that for oligomeric/polymeric PFAS immunotoxic effects were shown, but only states evidence concerning oligomeric PFAS. (Annex B.5.2.1.5, p. 165).

- As for developmental effects and fertility effects in experimental animals, no studies observing developmental toxicity are known for oligomeric/polymeric PFAS (Annex B.5.2.2.1., Annex B 5.2.2.2, p. 168).

- With regard to carcinogenicity, the proposal on the one hand quotes studies that found carcinogenic effects regarding polymeric PTFE. On the other, however, there is no evidence for such effects for other Fluoropolymers and for PFAS in general the proposal states, that human relevance of carcinogenicity of most PFAS is unclear (Annex B.5.2.3, p. 169).

- Regarding immune outcomes, the proposal sees evidence between PFAS and common infectious diseases, even though it states, "that more studies with objective measures of infections (not self-reports) are needed" and that "there are inconsistent findings" (Annex B, p. 171) regarding upper respiratory tract infections. In fact, this seems to be contradictory.

(50) Moreover, the Proposal is not even able to justify a hazard to human health with regard to non-polymers, for which studies are available more commonly. It remains vague in various places and does not describe any clear scientific statements. For example, it is taken as evidence that absorption through the skin cannot be excluded, because small insignificant increases of plasma fluoride concentrations after dermal absorption of PCTFE oligomers were shown in rodent urine and plasma (Annex B.5.1.2, p. 155).

(51) Against this background it needs to be concluded that the Proposal fails to demonstrate hazard properties of Fluoropolymers with respect to human health effects. Insofar, the prerequisites according to Article 68(1) REACH are not met.

c) Hazard to environment

(52) Also, there is no conclusive scientific evidence that Fluoropolymers have hazard properties with respect to effects to the environment.

aa) General considerations

(53) Regarding ecotoxicity, the main part of the Proposal only states that there is evidence for (just) a subset of PFAS and because of the large number of different substances with heterogenous properties (e.g. due to different functional groups) in the group of PFAS the assessment of their ecotoxicity is very complex (cf. Proposal, p. 28). On a more detailed level, Annex B of the Proposal concludes that the available data on adverse effects of PFAS in the environment is limited to a small number of substances (B.7.1.11, p. 202). According to the Proposal, conventional ecotoxicological tests may not be suitable to detect long term effects from exposure to PFAS and the small subset of PFAS, for which such information is available, contains PFOA and PFOS (B.7.1.11, p. 202). Accordingly, there is no evidence or proof that Fluoropolymers pose any risk to the environment at all.

(54) In this respect, it is not sufficient or convincing that the proposal states, that due to certain properties of PFAS it is not possible to demonstrate safe use of PFAS (B.7.1.11, p. 202). Contrary to the dossier, it cannot be concluded that this warrants for a restriction.

To the contrary, Article 68(1) REACH clearly states that there has to be a risk to the environment and, as stated above, any such risk needs to be identified on basis of a sufficient hazard assessment. If a risk to the environment cannot be concluded from available scientific data regarding hazard properties of the substance(s) within the scope of a proposed restriction, the provisions of Article 68(1) REACH are not fulfilled. A restriction under REACH is not a legitimate legal consequence if based on mere assumptions. To the extent that the Proposal (B.7.1.11, p. 202 et seq.) also points to the fact that future contamination is irreversible, it evidently fails to recognize that mere irreversibility in itself does not represent an environmental hazard and is only relevant in connection with other hazards, which, however, are not identified on basis of relevant scientific evidence for Fluoropolymers.

(55) With respect to the effects on wildlife, the proposal concludes that the available studies provide evidence, that PFAS can cause adverse effects on wildlife species at currently relevant concentrations (Annex B.7.2.8., p. 207). This is wrongful, since according to the proposal, due to the limitations of the studies, a clear link between PFAS measurements in the environment, or PFAS-body-burdens in the animals and the observed effects can rarely be established (ibid.). Furthermore, it is stated that laboratory studies that can plausibly link effects in these species to PFAS exposure would be needed but are in most cases not available (ibid.). This contradiction is justified by the Proposal with a precautionary approach. However, this consideration is not convincing, because the precautionary principle requires reliable scientific data and logical reasoning, leading to a conclusion which expresses the possibility of occurrence and the severity of a hazard's impact. Such an assessment has not been conducted in the present case, in particular not with respect to Fluoropolymers.

(56) As to the atmospheric compartment, only fluorinated gases are considered to be problematic, i.e. no specific hazard property has been identified with respect to Fluoropolymers in this regard.

(57) With respect to endocrine activity and endocrine disruption, the proposal summarizes, that "indications" of interactions of "some" PFAS with the endocrine system of environmental species, adverse effects (some occurring cross-generational), and "first observations of possible influences" of PFAS body-burden on hormone levels in wildlife raise concerns about the presence of PFAS in the environment (Annex B.7.5.3.4., p. 218) and that adverse effects "cannot be excluded" (cf. Proposal, p. 28). Again, the wording clearly shows, that there is no conclusive evidence for any hazard and especially no conclusive evidence for a hazard with regard to every substance within the scope of the proposal, e.g. Fluoropolymers. As before, the proposal argues for a hazard with the persistence of the substances. Insofar, the above stated considerations again apply *mutatis mutandis*.

(58) With regard to LRTP, the dossier concludes that many PFAS have potential for long-range transport mainly due to their high persistence (p. 25; Annex B.4.2.8., p. 112). However, according to the dossier, for the majority of PFAS no data on transport pathways

or point sources are available and thus substantial uncertainties on the concern of the long-range transport potential remain (Annex B.4.2.8., p. 112). As for accumulation in plants, it is stated that studies on accumulation of PFAS in plants are lacking for the majority of PFAS and that, while it is indicated that PFAS have the property to enrich plants, it remains unclear if all substances/subgroups may have this property (Annex B.4.4., p. 134, 135). Available data (as summarized in *Henry* et al., loc. cit.) Fluoropolymers are insoluble in water and LRTP is completely ruled out. Accumulation of fluoropolymers in plants is unthinkable due to their unique properties.

bb) Assessment of environmental hazard properties of Fluoropolymers

(59) The proposal comments on the hazard characteristics of Fluoropolymers in a special section (B.7.6., p. 219 et seqq.) and states, that Fluoropolymers themselves can pose an environmental hazard. However, there is no sufficient evidence presented in this regard. For example, with regard to toxicity, conflicting studies are cited (see B.7.6.1., p. 220). Furthermore, the dossier admits, that the bioaccumulation potential for polymers in general is poorly understood so far and cell membrane penetration "cannot be excluded" (ibid.), while no further evidence is provided.

(60) Apart from that, the dossier mainly refers to the hazard properties of microplastics, which is insufficient for several reasons. First, the dossier does not state any relevant intersections of Fluoropolymers and microplastics. This is quite astonishing because it is the only section in the entire dossier where reference is not made to specific PFAS or PFAS in general, but to a distinct category. Obviously, evidence presented for microplastics is not relevant in the current context, since there is no evident connection established between the category "Fluoropolymers" and the category "microplastics". Second, there has been a restriction process for microplastics in the past. Therefore, any evidence regarding microplastics seems to be brought forward either in the wrong restriction procedure or the Proposal at hand would result in an illicit double-regulation of the same matter. Third, and foremost, the current Proposal quotes the former RAC opinion regarding microplastics saying that, although there are uncertainties in the understanding of the hazard and risk of microplastics, there is sufficient evidence to conclude that they constitute an intrinsic hazard because of their persistence in combination with their potential to cause adverse effects. This consideration fails to meet the criteria and procedure set out in Article 68(1) REACH. Fourth, according to the dossier, several studies have investigated adverse effects of microplastics in general and no negative effects on population level have been demonstrated so far. Moreover, Microplastics are generated due to surface friction or abrasion whereas fluoropolymers like PTFE have the lowest coefficient of friction. Also, the concerns related to microplastics are connected to commodity uses of 100s of millions of tons of general plastics whereas fluoropolymers are mostly used in industrial applications and their global consumption is estimated at less than 350,000 tons. Comparison between microplastics and fluoropolymers is untenable, first due to the property of required friction and second due to the difference in consumption volumes particularly for commodity applications.

(61) In conclusion, the dossier fails to establish any relevant evidence that Fluoropolymers pose a risk to the environment. The mere persistence is not sufficient and moreover, the proposal states that persistence is only well known for some Fluoropolymers (B.7.6.3., p. 221 et seq.). Therefore, even according to the logic of the submitters, there is no evidence for hazard properties for the entire group of Fluoropolymers.

cc) Failure to establish persistence as such as (environmental) hazard

(62) Additionally, it needs to be noted that the Proposal is also unlawful insofar as it aims to establish risks to the environment by mainly referring to the persistence of the substances within the scope of the intended restriction. With respect to environmental hazards, the Proposal itself states that there is evidence for only a subset of PFAS and that, because of the large number of different substances with heterogenous properties in the group of PFAS, the assessment of their ecotoxicity is very complex (cf. Proposal, p. 28). Consequently, for the vast majority of PFAS, the only environmental property presented by the Proposal is "persistence" as defined in a broad and general manner. This approach, however, is unlawful for a variety of reasons.

(63) Persistence as such does not qualify as a hazard property but is merely a physical and chemical property of a substance based on the identification of the degradation potential due to the half-life of a substance under various conditions. As a physical and chemical property, persistence alone does not qualify as an environmental hazard because persistence alone cannot cause or result in environmental effects. The mere persistence of a substance, therefore, simply means that a substance with this property exists for a long time. This finding also follows from the Proposal itself, i.e. is in line with the view of the Dossier Submitters.

(64) With reference to the environmental aspects of any hazard assessment, testing will be used to determine the physical and chemical properties of a substance to identify and indicate the fate of the substance in the environment. This holds true for criteria like persistence, degradation or mobility. Only as a separate step, and with a set of different studies, potential environmental effects of a substance can be identified, like e.g. aquatic toxicity, mammalian toxicity, etc. The headings in Annex B to the Proposal only refer to defined environmental hazards such as ecotoxicity and effects on wildlife (cf. Annex B.7.), while persistence is discussed in the context of the "environmental fate properties" (cf. Annex B.4). Therefore, already systematically persistence is not considered as a hazard property relevant to the mandatory environmental hazard assessment. If mere persistence would already be considered as an environmental hazard, many other substances would also qualify for further regulatory measures. Such approach on a "P-only" basis is not supported by REACH or any other regulatory framework on EU level. Not even the most recent amendments under CLP support hazard classification on basis of the persistence of a substance, but only if further properties can be identified.

(65) As far as the Proposal attempts to justify the existence of e.g. potential ecotoxicity or effects on wildlife in the context of the environmental assessment (cf. e.g. Proposal, Annex B.7.5.3.4., p. 218), it does so on basis of the assumption that there is a need for action because all PFAS within the scope are considered to be persistent and, therefore, any consequences would be irreversible, while the Dossiers Submitters nonetheless acknowledge that there is insufficient evidence for relevant environmental hazards which can be attributed to any and all PFAS within the scope of the Proposal, including Fluoropolymers.

(66) We therefore submit that the justification provided with the Proposal is invalid from a systematic point of view and does not support the inclusion of Fluoropolymers. The REACH Regulation does not contain any provision which states that the reversibility of a condition is important in connection with an environmental hazard assessment. Rather, it is the genuine task of the environmental hazard assessment to determine whether a given substance has intrinsic hazard properties. If this determination cannot be made, it is contradictory to presume environmental hazards simply because, in theory, a substance may be persistent and it may, in some respects, difficult to take countermeasures (referred to in the proposal as "threat of irreversible damage", cf. for example Annex B.7.5.3.4., p. 218). With this approach, the Proposal fails to demonstrate a sufficient hazard assessment as required for the preparation of a dossier in accordance with Annex XV to REACH and, consequently, no environmental hazards are demonstrated in an appropriate manner if the Dossier Submitters base their conclusion merely on the purported persistence of all PFAS alone.

(67) Such an approach can also not be justified with a mere reference to the precautionary principle. It follows already from Commission Communication COM(2000) 1 of 2 February 2000 that the precautionary principle should be considered within a structured approach to the analysis of risk which comprises three elements: risk assessment, risk management and risk communication. It is commonly acknowledged that the precautionary principle comes into play subsequent to a risk assessment and, thus, where scientific information is insufficient, inconclusive, or uncertain and where there are indications that the possible effects on, inter alia, the environment may be potentially dangerous and inconsistent with the chosen level of protection. The precautionary principle, however, does not excuse the need for scientific information as a basis for a risk assessment in the first instance in favour of simply presuming that persistence equates to unacceptable risk.

(68) As far as the Proposal (B.7.6.1., p. 219 et seq.) indicates that an intrinsic property results in a relevant hazard property due to mere persistency and additional further properties - as already supported in the restriction of microplastic – such argumentation has to be rejected as incorrect.

(69) This argumentation fails because it deliberately circumvents the criteria of Article 68(1) REACH. It fails to recognize that there must be an unacceptable risk to the environment

for a restriction to be imposed in the first instance. If one were to dispense with this requirement, the result would be that a broad variety of substances could be restricted, because many substances are present in the environment in ever greater quantities due to continuous use and associated release, and for many of these substances there is also no possibility of removing them from the environment. In other words: If only the potential irreversibility of the condition and not the actual harmful effects on the environment are taken into account, Article 68(1) REACH would be interpreted in way which exceeds its actual wording.

(70) We further submit in this context, that such an approach results in a deviation from the prerequisites set out in Article 68(1) REACH. Insofar, the Proposal also infringes the principle of good administrative behaviour as well as legitimate expectations of market actors as it would not be possible to reasonably foresee whether a substance could and potentially would be restricted.

d) Need to provide evidence for a hazard to human health or the environment for every subgroup

(71) It has, therefore, been shown that Fluoropolymers do not pose a risk to human health or the environment. As a precaution, it must be pointed out that the lack of corresponding scientific evidence for the identification of respective hazard properties and, as a consequence, the existence of a relevant risk within the meaning of Article 68(1) REACH, cannot be justified by the grouping approach. It is true that a restriction may regulate several substances at the same time, provided that the relevant requirements on grouping are met. However, this does not justify a deviation from the requirement to demonstrate compliance with the legal requirements for a restriction at least for each subgroup. The guidance document on groupings does not state at any point that lower evidence requirements apply in this respect. This applies in particular against the background that Fluoropolymers are treated in the proposal, as can be seen in Annex B.7.6 or the proposed Annex XVII entry, as a special PFAS category with special properties and circumstances that characterize them. While it may be justifiable with regard to the group-based approach for individual substances to dispense the requirement for individual, substance-based evidence, such an approach cannot be considered permissible for a whole, high-profile subgroup. It is contradictory to the teleological background of the group-based approach that a group of substances, which is distinct from the other substances covered, is considered as belonging to a broader group so that the need to established a concrete proof of hazard properties is waived.

e) No „justified" uncertainties and incorrect handling of uncertainties

(72) As a precautionary note, it should also be noted that the absence of hazardous properties cannot be justified by the fact that uncertainties are concerned and that such uncertainties are quite legitimate in the context of restriction procedures. This is because, on

the one hand, in this respect the Dossier Submitters do not comply with ECHA's requirements for dealing with such uncertainties.

(73) In this respect, it needs to be noted that the respective uncertainties are not uncertainties concerning the scientific evaluation of a certain question, i.e. hazard properties, but self-inflicted uncertainties which are solely due to the selected approach to cover a huge, non-homogeneous group of substances with the scope of the restriction proposal. For this reason, the Dossier Submitters cannot refer to the position that specific uncertainties are a regular part of every restriction dossier.

(74) This notwithstanding, the Proposal contains a remarkably high number of uncertainties regarding the analysis and assessment of claimed hazards of PFAS, which are ultimately caused by the lack of sufficient scientific studies. When presenting these uncertainties, in some cases the Dossier Submitters did not adhere to the formal principles established by the document „Description of uncertainties in the evaluation of restriction proposals" by the Restriction Task Force (endorsed at the CARACAL-35 meeting on 31 March 2020, hereinafter referred to as "**Guidance on uncertainties**").

(75) Compliance with these formal requirements already by the Dossier Submitters is by no means a mere formality, since according to the guidance document, RAC and SEAC have to indicate in their opinions regarding the dossier whether and to what extent the existing scientific data do not allow for a complete hazard assessment. This, in turn, should enable the Commission in the further course of the procedure to apply the precautionary principle in an appropriate manner when deciding whether restriction measures should be taken. The dossier fails to comply with the respective document in some important respects, as shown as follows.

(76) According to the Guidance on uncertainties, the Dossier Submitters should have clarified which elements are uncertain. This requirement relates to, inter alia, hazards, uses, emissions, availability of alternatives and technologies, and the assessment of the socio-economic impacts of the restriction (cf. Guidance on uncertainties, p. 2). In the present case, deficits are particularly evident in the case of Fluoropolymers. For example, the Dossier Submitters on the one hand admit that no studies are known on the persistence of Fluoropolymers under environmental conditions (Annex B, p. 219) but, on the other, proceed to regard persistence as already proven (for example Annex B, p. 218). This contradiction would have required a precise presentation of the uncertainties. The lack of such a precise presentation will consequently also have an impact on the quality of the opinions to be established by RAC and SEAC.

(77) Furthermore, the Dossier should indicate the extent to which remaining uncertainties affect the conclusions drawn (cf. Guidance on uncertainties, p. 2). For example, regarding the mobility of PFAS, the dossier states that there is insufficient data, but it is not clear how this insufficient data is reflected in the subsequent conclusion (see Annex B, p. 79).

Insofar, the Dossier does not comply with the rules set out in the respective guidance document.

(78) Another requirement for a dossier is to indicate the timeframe and costs to be expected in order to fill the identified gap through additional scientific studies (cf. Guidance on uncertainties, page 2). This is related to the consideration that, within the framework of the precautionary principle, the Commission could order further studies instead of deciding for a restriction. Again, the dossier fails to comply with this requirement. For example, within the conclusions for environmental monitoring in Annex B.4.2.7.10. (p. 104) it is made clear that "significant fractions of organofluorine in environmental samples are unknown and are therefore not captured by monitoring using only targeted PFAS analysis". Contrary to the requirements, however, it is not stated whether more precise findings on this are to be expected from further studies and, if so, what duration and costs are to be expected in this respect. There are also uncertainties regarding the toxicity of polymeric PFAS in animal experiments, which are due to insufficient data. However, the Dossier Submitters do not give an outlook on future data collection or its costs and duration (Dossier, Annex B p. 154). Furthermore, it is conceded that further studies are required, without specifying their predicted time span (Annex B, page 116).

(79) Overall, the requirements laid down in the Guidance on uncertainties are not met for various reasons. This complicates the further proceedings, in particular because it is unclear which uncertainties are relevant and have to be solved, e.g. by commissioning further studies, and which uncertainties can remain as regular part of any science-based evaluation. However, the mere identification of uncertainties without further description or information can by no means suffice.

f) Insufficient hazard assessment regarding new hazard classes

(80) The aforementioned inconsistencies regarding the hazard assessment of PFAS within the scope of the Proposal, in particular with respect to Fluoropolymers, also hold true against the background that the proposal refers to the mobility of PFAS. The assumed mobility of PFAS is clearly not derived from the intrinsic properties of the substances within the defined scope, i.e. properties which the substances may have individually to varying degrees in and of itself. It is rather the exposure of the substances and their potential availability especially in water compartments that supports the criterion against the background of the outline provided with the Proposal. The mere fact that PFAS might emerge in the aquatic environment, however, is not linked to any intrinsic property of the substances but qualifies as a result of their (presumed) persistence and an assumed availability in the water cycle. The Proposal, however, fails to sufficiently consider the fact that Fluoropolymers do not dissolve in water and therefore are not mobile.

(81) This also holds true with respect to the further considerations outlined in Recital (8) of Commission Delegated Regulation (EU) 2023/707. Nothing in this Delegated Regulation

can additionally support the Proposal. The aforementioned Delegated Regulation introduced, inter alia, new hazard classes for substances being identified as PMT (persistent, mobile, toxic) and vPvM (very persistent, very mobile). But according to the Recital (8) of the Delegated Regulation, PMT and vPvM criteria mainly focus on persistence and mobility, whereby the overall basis for the introduction of the corresponding hazard classes is the mere fact that such substances

> *"can enter the water cycle, including drinking water, and spread over long distances. Many PMT and vPvM substances are only partly removed by wastewater treatment processes and can even break through the most advanced purification processes at drinking water treatment facilities. Such incomplete removal coupled with new emissions mean that the concentration of those PMT and vPvM substances in the environment increase over time. Once released into the environment, exposure to PMT and vPvM substances is difficult to reverse, which leads to cumulative exposure of both animals and humans via the environment. Any effects from this exposure are unpredictable in the long-term."*

(82) Insofar, the underlying justification for the introduction of the hazard classes PMT and vPvM is similar to the justification provided for in the Proposal. We submit, however, that this Delegated Act has been adopted by the Commission in misuse of powers conferred to the Commission according to the CLP Regulation and, therefore, the newly introduced hazard classes cannot justify the proposed restriction or support the risk assessment outlined therein.

(83) The Commission is only empowered under the CLP Regulation to adopt delegated acts in accordance with Article 53a of CLP to amend Articles 6(5), 11(3), 12 and 14, 18(3)(b), 23, 25 to 29, 35(2) subparagraphs 2 and 3 and Annexes I to VIII of CLP for adaptation to technical and scientific progress, taking due account of the further development of the Globally Harmonised System ("GHS"), in particular any amendments at level of the United Nations relating to the use of information on similar mixtures, and taking into account developments in internationally recognized chemical programs and data from accident databases. The amendment of the CLP Regulation to introduce new hazard classes does not fall under these powers.

(84) Although the Proposal does not specifically refer to the contemplated new hazard classes due to the fact that the respective delegated act was published in the Official Journal of the EU only on 31 March 2023 (OJ of 31 March 2023, L 93, p. 7) the corresponding prerequisites and criteria are nonetheless applied. Due to the misuse of powers, however, the Delegated Act cannot be used to justify or support the Proposal. This moreover as the Proposal was established even prior to the entry into force of Commission Delegated Regulation (EU) 2023/707.

2. Failure to meet the prerequisites established in Article 68 REACH regarding risk assessment

(85) As stated above, an unacceptable risk within the meaning of Article 68(1) REACH is formed of a hazard to human health or the environment and a relevant exposure. The dossier not only fails to proof such hazard and, therefore, any further risk assessment already lacks a sufficient basis.

a) Insufficient evidence regarding exposure to Fluoropolymers.

(86) Any risk assessment needs to be based on identified hazard properties and relevant exposure to the substance at hand. With respect to Fluoropolymers, the Proposal is already lacking a sufficient assessment of respective hazard properties. But also the identification of related exposures is not convincing. For example, according to the proposal, very little is known about the levels of polymeric PFAS in the environment (cf. Proposal, p. 45). As for human exposure assessment, the proposal states, that the bioavailability and thus the potential for human exposure to Fluoropolymers has been an issue for discussion (cf. Proposal, p. 46). Thus, according to the Proposal, it has been proposed that absorption of Fluoropolymers in humans is obstructed due to their large sizes (Henry et al., 2018).

(87) Despite these findings, it has been argued that the production, processing, use, and end-of-life treatment of Fluoropolymers lead to emissions of bioavailable compounds (ibid.). In sum, there seems to be no clarity regarding the exposure to Fluoropolymers.

(88) And even if one would consider it appropriate to consider corresponding risks with respect to the use of fluorinated polymerisation aids used for the manufacture of Fluoropolymers, although the underlying hazard assessment is lacking sufficient evidence, it would have been possible and sufficient to propose a restriction for the use of fluorinated polymerisation aids qualifying as PFAS in connection with the manufacture of Fluoropolymers. The manufacture and use of Fluoropolymers as such, however, should not be included in the scope of the Proposal, i.e. an exemption or non-time-limited derogation would be justified. Also because more than 50% of commercially produced fluoropolymers do not require the use of any polymerization aids let alone fluorinated polymerization aids (cf. *Sales* et al., ICRL 2022, p. 13, 19 with further references).

b) Deviation from principles for risk assessment

(89) With respect to risk assessment requirements as set out in Article 68(1) REACH, the Proposal itself demonstrates a deviation from applicable principles. The Proposal states that the procedures in Sections 1 to 6 in Annex I to REACH are impracticable to describe the particular effects of PFAS within the scope of the restriction proposal, as the PFAS in scope are very persistent in combination with identified and possible other concerns. Therefore, the Proposal states that the respective risk is described on a case-by-case basis as reflected in Section 0.10 of Annex I to REACH.

(90) The Proposal, however, ignores the fact that already the wording of Section 0.10 of Annex I to REACH states that (only) in "relation to particular effects, such as ozone depletion, photochemical ozone creation potential, strong odour and tainting, for which the procedures set out in Sections 1 to 6 are impracticable, the risks associated with such effects shall be assessed on a case-by-case basis". Against this background, it is against the law that the entire risk assessment for all hazard properties and all corresponding exposures is carried out on a case-by-case basis. Moreover, a "case-by-case" approach according to Section 0.10 of Annex I to REACH is established as a more specific and tailored approach for certain effects. The corresponding section does not support the view that a deviation from Sections 1 to 6 of Annex I to REACH is also possible to establish a broad and generic restriction proposal and to circumvent a possible, although complex and potentially difficult assessment according to Sections 1 to 6 of Annex I to REACH. Rather, the wording of Annex I suggests that a case-by-case approach is only intended in justified individual cases and only for certain effects. These requirements are not met with respect to PFAS, not even in the view of the Dossier Submitters.

(91) As is demonstrated with the further evidence provided as part of the broader submission of GFL, a risk assessment according to Sections 1 to 6 of Annex I to REACH would have resulted in the conclusion that manufacturing and use of Fluoropolymers do not entail a risk in accordance with Article 68(1) REACH.

(92) But even if a case-by-case approach according to Section 0.10 of Annex I to REACH would be considered appropriate with respect to PFAS, including Fluoropolymers, it needs to be noted that "a full description and justification of such assessments" still would be required. Deviating from the general approach for a risk assessment in line with Section 1 to 6 of Annex I to REACH and applying a restriction-specific assessment cannot circumvent the requirement to establish sufficient scientific evidence and justification that environmental hazards actually are present. Mere presumptions and referenced possibilities do not qualify as a sufficient basis. Therefore, the Proposal erroneously follows a route for the hazard assessment, which is not supported by the REACH Regulation and, thus, cannot justify the proposed restriction.

(93) Therefore, it must be concluded that the Proposal is lacking sufficient evidence and justification as to why all PFAS have intrinsic properties which result in environmental hazards. The Proposal does not comply with Article 68(1) REACH and erroneously deviates from applicable statutory requirements and established guidance. By doing so, the Proposal breaches the principle of good administration and legitimate expectations.

(94) The Proposal and the underlying justification deviates from statutory prerequisites and established guidance. Due to this deviation, it is not only difficult to identify the specific scientific basis for the conclusion as to why any and all substances within the scope of the Proposal do have relevant hazard properties that result in a relevant risk as required by Article 68(1) REACH. Insofar, the Proposal infringes the principle of good administration due to inconsistency of the underlying administrative behaviour and a breach of

legitimate expectations of stakeholders and other market actors regarding the proceeding, the underlying assessment, and the intended decision-making process.

3. Unlawful grouping

(95) Although various inconsistencies of the grouping as referred to in the Proposal are already demonstrated with respect to the hazard and risk assessment, as outlined above, we further submit that the grouping of all known and unknown PFAS as proposed by the Dossier Submitters is unlawful.

a) Deviation from available guidance

(96) In the respective guidance document, it is stated, that grouping could be considered

> *"when the key property in combination with the exposure that causes the risk leading to the proposal of a restriction is shared by several related substances"*

(cf. Guidance for the preparation of an Annex XV dossier for restrictions, p. 23). As is apparent from the wording, the substances do not only need to share the same property or properties but also, in effect, the same risk. In the present case, the PFAS within the scope of the Proposal share, according to the Proposal itself, one single property, i.e. persistence, which as such does not even qualify as a hazard property.

(97) While the Dossier Submitters emphasize that this is the relevant key property, we submit that persistence as such does not qualify as a hazard property nor as a risk. Therefore, persistence as such is not a sufficient basis for a grouping approach. According to the Proposal (cf. p. 22), the additional properties of PFAS differ and vary among the PFAS, while it is not even demonstrated that any and all PFAS within the scope of the Proposal have additional hazard properties beyond their persistence at all. A common hazard property and profile and, thus, any substantially similar risk shared by all substances within the scope of the Proposal cannot be established and the Proposal does not even claim to achieve the applicable prerequisites for grouping. Consequently, the requirement for grouping is not met, and the Proposal is further legally deficient on this basis.

(98) Besides not meeting the criteria as laid down in the respective guidance document, the group-based approach is erroneously established for another reason. The background of this approach is that different substances can and should be examined together on the basis of similarities, in particular to improve the effectiveness of the restriction and the procedure (cf. Grouping of substances to be covered in a single restriction dossier (Restriction Task Force), p. 1). It is true that the PFAS within the scope of the proposal arguably all show some persistence. However, the numerous scientific uncertainties do not arise with regard to the question of persistence, but rather with regard to any potential additional hazardous properties. In this respect, the Proposal itself states that there are major differences between the PFAS covered (Proposal, p. 22). However, this undermines the conceptual origin of the group-based approach. Indeed, if no reciprocal

links can be established with respect to the issues at stake, there are no efficiency gains from the process. Moreover, the group-based approach in the present case leads to the conclusion that the properties of certain PFAS are related to the properties of other PFAS, without this being scientifically substantiated (cf., representative of many examples, for example Proposal, Annex B, page 181). Logically, such cross-references should take place precisely for the common property and precisely not with regard to such properties, which differ greatly. In this respect, the group-based approach is not persuasive. This specifically holds true with respect to the distinct sub-group of Fluoropolymers.

(99) Against this background, the grouping can also not be justified by the fact that a regrettable substitution should be prevented. For example, with regard to Fluoropolymers, the extent to which such substitution behaviour would be possible at all has not been established. Furthermore, the consideration is not proportionate, especially with regard to substances that are still completely unresearched, because it does not make any gradation between more dangerous and less dangerous substances. It is evident that there are more dangerous and less dangerous PFAS. In this respect, in order to maintain proportionality, certain groups of PFAS could have been included in the restriction proposal with the aim of displacing the market and certain other PFAS, whose effects on humans and nature have been proven to be low, could have been excluded from the scope. This is especially true in light of the fact that certain persistent substances will continue to be needed in industry in the future. For these uses, a persistent alternative must inevitably be available, so that in terms of proportionality it should have just been enshrined to allow certain substitutions instead of restricting all PFAS with the argument of preventing any "regrettable substitution".

(100) Moreover, specifically with respect to Fluoropolymers, it is impractical and ultimately erroneous to have them regulated together with other PFAS. This is because the dossier shows in several sections that it considers Fluoropolymers to be a special, distinct category of PFAS. An example of this is the specific environmental hazard assessment for Fluoropolymers in Annex B.7.6 (p. 219 et seqq.), in which it is significantly stated that the main problem of Fluoropolymers lies in the release of other PFAS. The dossier thus admits that Fluoropolymers as such do not have the same intrinsic hazard properties as other PFAS. In this respect, it is legally incorrect that Fluoropolymers are treated the same way as other PFAS and, thus, are subject to conclusions derived from hazardous properties of other PFAS due to the group-based approach.

(101) This applies in particular against the background that Fluoropolymers - compared to all other PFAS - are partially treated as microplastics in the dossier. Furthermore, the proposal of the restriction text also shows the autonomy of the category of Fluoropolymers, because special derogations apply to them (cf. proposed restriction, Column 2, Nos. 6 and 8). In particular, according to Column 2, No. 8 of the proposed restriction, only Fluoropolymers are subject to certain further information requirements in the event that a derogation is used. This is contradictory in itself, because an exemption actually presupposes sufficient information.

(102) Above all, however, this distinct approach shows that there are obviously major knowledge gaps for Fluoropolymers. Against this background, too, it seems absurd to regulate Fluoropolymers together with other PFAS such as PFCAs, PFOA, for which corresponding information on the hazardousness is actually available. Due to the already acknowledged difference between Fluoropolymers and other PFAS, the principle of the rule of law requires that Fluoropolymers are regulated separately if a corresponding regulatory measure is justified at all.

b) Grouping not justified with respect to PFAS definition established by OECD

(103) The grouping approach as applied in the Proposal can also not be justified with the definition of PFAS as established with OECD guidance "Reconciling Terminology of the Universe of Per- and Polyfluoroalkyl Substances: Recommendations and Practical Guidance" ("**OECD (2021)**").

aa) PFAS definition according to OECD

(104) Prior to the assessment of the justification of the grouping approach it needs to be noted that the perception and definition of PFAS as established by the OECD were subject to some major changes in recent years.

(105) In Buck et al. (2011), PFAS were defined as "the highly fluorinated aliphatic substances that contain 1 or more C atoms on which all the H substituents (present in the nonfluorinated analogues from which they are notionally derived) have been replaced by F atoms, in such a manner that they contain the perfluoroalkyl moiety CnF2n+1–" (i.e. must contain at least –CF3). The definition highlights the presence of at least one fully fluorinated saturated carbon atom in the PFAS molecules.

(106) PFAS were re-defined by the OECD in 2021 as follows:

> *"PFAS are defined as fluorinated substances that contain at least one fully fluorinated methyl or methylene carbon atom (without any H/Cl/Br/I atom attached to it), i.e. with a few noted exceptions, any chemical with at least a perfluorinated methyl group (–CF3) or a perfluorinated methylene group (–CF2–) is a PFAS."*
>
> (OECD (2021), Reconciling Terminology of the Universe of Per- and Polyfluoroalkyl Substances: Recommendations and Practical Guidance, OECD Series on Risk Management, No. 61, OECD Publishing, Paris, p. 8)

(107) According to the OECD, the introduction of the new definition is triggered by two main reasons (cf. OECD (2021), p. 7, 18). First, the OECD/UNEP Global PFC Group prepared a new list of PFAS that may have been on the global market in 2018. In total, a set of substances with over 4.730 CAS numbers have been identified, including substances that contain fully fluorinated carbon moieties, but do not meet the PFAS definition in Buck et

al. (2011) due to a lack of a –CF3 group in the molecular structures. Second, according to the OECD, recent advancement of non-target screening analytical techniques using high-resolution mass spectrometry has enabled identification of many unknown substances in different environmental and product samples. Thus, the development and broaden of the definition is motivated by the identification of overlooked PFAS (cf. OECD (2021) p. 18) and the closing of identified gaps in the previous PFAS definition (cf. OECD (2021) p. 21, 23).

(108) Furthermore, according to the OECD, the rationale behind the revision is to have a general PFAS definition that is coherent and consistent across compounds from the chemical structure point of view and is easily implementable for distinguishing between PFAS and non-PFAS, also by non-experts (OECD (2021), p. 8). The OECD claims, that the decision to broaden the definition is not connected to decisions on how PFAS should be grouped in regulatory and voluntary actions (ibid.) and that the intention of the revision of the PFAS definition is not to expand the PFAS universe, but to comprehensively reflect it (OCED (2021), p. 23).

(109) The OECD states, that the term "PFAS" is a broad, general, non-specific term, which does not inform whether a compound is harmful or not, but only communicates that the compounds under this term share the same trait for having a fully fluorinated methyl or methylene carbon moiety (OECD (2021), p. 8). Accordingly, the general definition of PFAS is based on molecular structure alone and serves as a starting and reference point to guide individual users to have a comprehensive understanding of the PFAS universe and to keep the big picture of the PFAS universe in mind (ibid.)

(110) The broadening of the definition is to be taken critically, since, in particular, it is contradictory and seems artificial. The justifications quoted above are subject to an error of logic. Ultimately, the OECD justifies the broadening of the definition by saying that PFAS overlooked by the former definition have been identified and that this gap is now to be closed.

(111) In this respect, it is already linguistically illogical that a definition is supposed to have "gaps" just because certain substances are not covered by it. According to this logic, every definition of a group of substances would logically have a gap, because some substances are of course not covered by the definition. Consequently, every definition would need to be broadened. This train of thought shows that the OECD's justification is not correct in this respect and, therefore, cannot justify a grouping approach for a restriction proposal under REACH.

(112) Moreover, the argument that new PFAS (!) have been identified in the meantime (e.g. by new screening methods) is illogical. After all, according to the definition applicable at the time, the substances identified were not PFAS by definition.

(113) Consequently, it is not a matter of closing gaps, but of expanding the definition. This is already clear from the fact that, as the OECD itself admits, the revised definition now

covers significantly more substances than before. Against this background, it is not comprehensible that the OECD states that the amendment of the definition was not intended to expand the universe of PFAS. After all, this is exactly what has happened by changing the definition in such a way that certain substances that were previously not covered by the definition, for example due to the absence of a –CF3 group, are now covered.

(114) As far as the OECD states that the new definition is necessary for a coherent and consistent distinction of PFAS, it fails to provide any evidence to what extent the previous definition was not coherent and not consistent. As already stated, the mere fact that certain, possibly even similar, substances are not covered by a definition does not make the definition inconsistent. On the contrary, it must be stated that the exclusion of certain substances from the definition has precisely shown that it functions and is therefore consistent and coherent.

(115) Thus, the impression arises that the OECD, contrary to its attempts at explanation, has changed the definition precisely because it wanted to classify the newly discovered substances as PFAS. As shown, the attempts to explain otherwise are not convincing. In particular, the reference to the fact that classification is based solely on molecular structure is also not sufficient. After all, it has not been shown whether and to what extent the previous definition was deficient in this respect. Overall, therefore, the conclusion remains that the OECD has significantly expanded the definition of PFAS for reasons other than those listed in the paper.

bb) OECD definition not based on hazard or risk assessment

(116) Furthermore, it has to be noted, that the broadening of the PFAS definition is not at all connected to any scientific findings of hazards or risks of certain substances but only based on chemical considerations (cf. OECD (2021), p. 31: does not include […] any other considerations beyond chemistry). This is remarkably, since the PFAS restriction proposal adopts (more or less) the definition and states that all substances within the scope of this definition are hazardous and thus must be restricted (Proposal, p. 22).

(117) It already follows from this misinterpretation of the revised OECD definition that the Proposal is flawed from a scientific and legal perspective. While the Proposal, on the one hand, acknowledges that the "OECD definition of PFASs is based on chemical structure" and hazardous properties or risks are not part of it" (cf. Proposal, p. 19) and, thus, some substances are excluded from the scope due to the fact that "they will ultimately mineralize in the environment" (ibid.), it needs to be noted, on the other, that the Proposal only presumes that all PFAS that remain within the scope of the restriction proposal "share a common hazard and risk", while a lack of scientific data on hazards for PFAS within the scope is broadly acknowledged. In other words, the Proposal is essentially based on the PFAS definition as established by the OECD which does not consider any hazard properties or risks, and the Proposal does not substantiate or justify for all substances within its scope if and which specific hazard properties apply. Therefore, the

Proposal is based on a non-hazard-/non-risk-based definition of the scope. Such approach is infringing the basis for a restriction proposal as established in Article 68(1) REACH and cannot be used to justify a grouping approach.

cc) Deviating scope of the restriction proposal does not justify grouping approach

(118) For the purpose of the restriction proposal, the Dossier Submitters define PFAS -compared to the OECD - slightly different as substances that contain at least one fully fluorinated methyl (CF3-) or methylene (-CF2-) carbon atom, without any H/Cl/Br/I attached to it. For the purpose of the Proposal, the Dossier Submitters propose the following scope (cf. Proposal, p. 14):

> *"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).*
>
> *A substance that only contains the following structural elements is excluded from the scope of the restriction: CF3-X or X-CF2-X',*
>
> *where X = -OR or -NRR' and*
>
> *X' = methyl (-CH3), methylene (-CH2-), an aromatic group, a carbonyl group (-C(O)-), -OR'', -SR'' or –NR''R''';*
>
> *and where R/R'/R''/R''' is a hydrogen (-H), methyl (-CH3), methylene (-CH2-), an aromatic group or a carbonyl group (-C(O)-)."*

(119) Thus, the Proposal introduces an exception which concerns certain fully degradable PFAS subgroups that contain some specific structural elements. PTFE is a fluoropolymer and it uses TFE (Tetra Fluoro Ethylene) and HFP (Hexa Fluoro Propylene) as raw materials. While TFE is not a PFAS as per the definition, HFP is. Such anomalies exist for other fluorinated monomers used in the production of fluoropolymers.

(120) Thus, the proposed scope of the restriction is a rather crude combination of the broad OECD definition and slight exemptions for subgroups which are considered to be not persistent by the Dossier Submitters. The derivation of the scope and its justification is, however, flawed for various reasons.

(121) As can be seen from the Proposal, the starting point for the development of the scope for the proposed restriction remains the OECD definition of PFAS. According to the proposal, the substance scope is "additionally" considered to be a concern-based one, which wants to cover all PFAS that are persistent (cf. Proposal, p. 19). For this reason, the Dossier Submitters exclude identified non-persistent subgroups from the scope, while it is not demonstrated that any relevant hazard or risk profile can be established for the remainder of the substances considered to be within the scope.

(122) It follows already from these considerations that the PFAS definition cannot justify a grouping approach. If it would be correct to assume that all PFAS within the scope, i.e. within the scope of the definition as established by the OECD, qualify as being persistent, it should not be possible to exclude certain PFAS as they cannot be considered persistent.

(123) But this notwithstanding, the Proposal only assumes that all PFAS, except for the few subgroups excluded from the scope, are persistent while this assertion is not substantiated in the justification of the scope of the Proposal or in any other section of the Proposal. To the contrary, the Dossier Submitters concede that they have no positive knowledge about the persistence of most substances, because they request stakeholders to prove that specific substances used by them are not persistent and can therefore be excluded from the scope (cf. Proposal, Annex B, p. 3).

(124) However, this approach does not meet the requirements of a diligent elaboration on the scope of a restriction proposal. This applies in particular against the background that the OECD has stated in the context of the justification of its extremely broad definition that, on the one hand, the broad definition cannot be connected to the scope of possible regulatory measures (p. 8), and, on the other hand, the definition is only a "starting point" due to its broadness (p. 31). It is true that the narrowing down of the definition to persistent substances, basically, can be considered a plausible refinement of the OECD definition. However, it would have been necessary to prove to what extent the many thousands of substances still covered within the scope are persistent, as far as this is considered the "main concern" (cf. Proposal, p. 24). By merely making an unsubstantiated claim, the scope (with the small exception of substances known to be non-persistent) corresponds nearly to the extremely broad OECD definition, which is clearly not based on a hazard or risk assessment.

(125) The aforementioned concerns especially hold true against the background that the OECD highly recommends that users clearly provide the context and rationale for selecting their PFAS working scope in order to provide transparency and avoid confusion by others (OECD (2021), p. 8). In the case at hand, such a rationale is not given except for the short statement that the aim is to address the concerns associated with the persistent nature of the substances (cf. Proposal p. 19).

(126) As a matter of fact, the Dossier Submitters, when justifying the scope of the restriction proposal, did not even bother to change the wording of the OECD paper which introduced the new definition. As an example, we would like to emphasize that the sentence

> "(…)*attracted much public attention since the late 1990s and early 2000s, when the hazards and ubiquitous occurrence in the environment of two PFAS, perfluorooctanoic acid (PFOA) and perfluorooctane sulfonic acid (PFOS), started to be reported and recognized*",

is taken from pages 7 and 17 of the OECD paper and is repeated on page 18 of the Proposal without indicating that it is a citation from the OECD paper and without source citation.

(127) Furthermore, it should be noted that the proposal only refers to persistence and not to hazards for humans or the environment. This is already questionable on the level of the elaboration of the scope, because persistence as such does not qualify as a hazard property as referred to in the REACH Regulation by reference to the CLP Regulation, and therefore not a suitable reference point for the mandatory risk assessment in accordance with Article 68(1) REACH.

(128) The mere fact that the OECD paper assumes that a limitation for potential regulatory measures is possible, *inter alia*, on basis of the criterion of persistency (OECD (2021), p. 26). However, against the background of the clear wording of Art. 68 REACH, this cannot apply to a restriction under REACH.

dd) Violation of OECD guidance on PFAS

(129) Furthermore, the Proposal violates the underlying OECD guidance because its wording does not meet the requirements laid down in chapter 3 of OECD (2021). In chapter 3.2, OECD (2021) gives a practical guidance on how to identify and use suitable PFAS terms. As stated in the guidance, it is strongly recommended that the PFAS terminology be used in a clear, specific and descriptive manner which is due to the fact that the term "PFAS" does not inform whether a compound is harmful or not, but only communicates that the compounds under this term share the same trait for having a fully fluorinated methyl or methylene carbon moiety (cf. OECD (2021), p. 32). A clear and specific wording is necessary to prevent ambiguity or factual errors. Thus, the OECD asks regulators to use terms that most clearly describe the substance(s) referred to in their statement and provides for concrete examples (cf. ibid.).

(130) The proposal violates these requirements in numerous points, of which only a few are listed below as examples.

(131) For example, it is linguistically extremely unfortunate that the Proposal, when developing the scope, does indeed clarify that certain (non-persistent) substances are excluded from the scope of the Proposal. This results in the scope containing only a subset of the substances that are to be considered as PFAS according to the current OECD definition. Nevertheless, the proposal refers in some places to "all PFAS" (e.g. Proposal, p. 22: "All PFAS are considered to be very persistent (...)") and thus leaves great linguistic ambiguity as to which substances are meant. Moreover, the above quoted passage is also fundamentally wrong as the proposal itself states that some PFAS are not persistent.

(132) A further linguistic inaccuracy is that in many places the term "some PFAS" is used (see e.g. Proposal p. 26, 35, 36, 48, 50; Annex B p. 133, 165, 208 and many more); in addition, sometimes a "subset of PFAS" is referred to (e.g. Proposal p. 28, 48). Both is entirely

insufficient against the background of the OECD's requirement to designate the respective substance or group of substances as accurately as possible.

(133) In addition, there are passages in the proposal in which the properties of specific substances or groups are first discussed (in accordance with the OECD specifications) and then generalized in the course of consideration. For example, the mobility is first explained on the basis of concrete substances and 5 paragraphs later the generalizing statement is made that "Mobility of PFAS in water contributes to their long-range transport potential (...)" (cf. Proposal p. 25).

(134) As a result, it must be stated that the Dossier Submitters did not comply with the requirements that emanates from the broad OECD definition. In many places they did not differentiate between PFAS in the sense of the definition and PFAS in the sense of the scope and, moreover, often made unnecessary generalizations. Insofar, the definition of PFAS as established with OECD (2021) and modified with the Proposal cannot justify the grouping approach due to the broad variety of inconsistencies.

4. Breach of principle of proportionality

(135) Furthermore, the proposal infringes the principle of proportionality for various reasons.

a) Availability of less onerous measures

(136) The proposal is disproportionate as there would have been less onerous measures to achieve the intended aim and purpose. According to settled case-law, the principle of proportionality, which is part of the general principles of EU law, requires that EU measures do not exceed the limits of what is appropriate and necessary in order to attain the objectives legitimately pursued by the legislation in question; when there is a choice between several appropriate measures recourse must be had to the least onerous, and the disadvantages caused must not be disproportionate to the aims pursued (judgments of 8 July 2010, Afton Chemical, C 343/09, EU:C:2010:419, paragraph 45; of 21 July 2011, Etimine, C 15/10, EU:C:2011:504, paragraph 124; and of 1 February 2013, Polyelectrolyte Producers Group and Others v Commission, T 368/11, not published, EU:T:2013:53, paragraph 75). The clearly communicated objective of the restriction proposal is to eliminate PFAS from the market as far as possible. Regardless of the question to what extent this is a legitimate goal, there would have been less onerous measures in several respects that would have served the goal with equal effectiveness.

(137) First, an authorization under Art. 55 REACH would have had to be considered. The ultimate aim of an authorization is that the use of substances of very high concern are replaced by suitable alternative substances or technologies where these are economically and technically viable (see judgment of 7 March 2013, Rütgers Germany and Others v ECHA, T 94/10, EU:T:2013:107, paragraph 134 and the case-law cited).

(138) Irrespective of the fact that the approach supported by the Dossier Submitters with the Proposal are in any case more similar to those of an authorization, an authorization obligation would have had the relevant advantage for stakeholders that they would have been provided with an orderly procedure for obtaining an authorization for their use. With the Proposal and the subsequent restriction procedure, stakeholders are now limited to requesting an exemption or derogation in connection with the consultation procedure. In this context it needs to be noted that the approach chosen by the Dossier Submitters leaves stakeholders in a less secured legal position.

(139) Other than in a regular authorisation procedure, there is no specific decision which is directly addressed to the applicant and which can be subject to further legal action if considered necessary in case of deviations from the underlying application. In the case at hand, however, a rejection of a request for an exemption or derogation does not even result in a decision addressed to the respective stakeholder and, even worse, the REACH Regulation does not even establish any legal prerequisite that a further justification for such rejection is provided. As no decision is adopted to that effect, not even the general principle to justify decisions would apply although this is enshrined e.g. in Article 18 of the Code of Good Administrative Behaviour for the Staff of the European Chemicals Agency (adopted by Decision of the Management Board MB/11/2008 of 14 February 2008, as amended by Decision of the Management Board MB/21/2013 of 20 June 2013) and the European Code of Good Administrative Behaviour (cf. C(2000) 3614, OJ L 308, 8 December 2000, p. 26).

(140) Even irrespective of the specific case at hand, which has the peculiarity that there must be different exceptions for many different uses, a restriction is generally the milder measure compared to the obligation to obtain authorization. It is true, however, that case law does not assume a special priority relationship between authorization and restriction in this respect. However, there is case law stating that a restriction is not (!) a less onerous measure compared to the identification of a substance for the candidate list (cf. Judgment of 25 September 2015, PPG and others vs. ECHA, Case T-268/10).

(141) This implies that the route via an authorization must in principle be considered as less onerous. Since the objective of the authorization and the objective of the restriction are otherwise identical, namely, with the exception of substances that are exempt from the restriction or have to be authorized, market elimination is to be achieved, the path via an authorization would have been a more proportionate measure in the present case.

(142) We understand that the Dossier Submitters identified various obstacles and regulatory shortcomings in connection with a potential authorisation approach for PFAS (cf. Proposal, Section 2.2.2.3, p. 69). We submit, however, that the aspects referred to in the Proposal in this context only address benefits for authorities as regards potential efforts which cannot justify deviations from the principle of proportionality.

(143) The Proposal already acknowledges that according to Article 58(3) REACH, priority for inclusion of SVHC in Annex XIV shall normally be given to substances with (a) PBT or vPvB properties, or (b) wide dispersive use, or (c) high volumes. While the Proposal also correctly states that only substances that were previously added to the Candidate List can be subject to authorisation requirements, the Proposal states that SVHC identification of all PFAS meeting the chemical definition would be very difficult (cf. Proposal, Section 2.2.2.3, p. 69). The Proposal, however, ignores the fact that already today a significant number of PFAS is included in the Candidate List (including but not limited to PFBS, PFHxS, PFHpA, PFOA, PFNA, PFDA, PFUnDA, PFDoDA, PFTrDA, PFTeDA). In addition, the Proposal conceals the fact that it would be possible to include all PFAS in the candidate list on basis of Article 57(f) REACH. If a corresponding grouping approach is considered feasible for the proposed restriction (regardless further concerns in this regard as already outlined above), the same approach could be used for SVHC identification. To that end, the template for corresponding Annex XV reports explicitly refers to the option to propose SVHC identification on basis of grouping.

(144) The same holds true for the prioritisation of SVHC for inclusion in Annex XIV as explicitly stated in ECHA's outline "General prioritisation approach: practical implementation examples" (Section 3, p. 4). Although no PFAS are listed in Annex XIV to REACH so far, nothing in the underlying procedural provisions would exclude this approach. The argument raised by the Dossier Submitters, that SVHC identification and subsequent inclusion in Annex XIV of all PFAS "fitting the chemical definition would be very difficult", is not convincing.

(145) Moreover, we submit that a decisive aspect has not been considered by the Dossier Submitters. With respect to enforcement, authorisation requirements seem to provide relevant advantages as all market actors using a substance would need to either apply for an authorisation or submit a notification according to Article 66 REACH, i.e. need to identify themselves and their respective uses vis-à-vis authorities. Enforcement of restrictions and corresponding exemptions or derogations do not require proactive identification of market actors and uses, which creates a significant likelihood of non-compliance on side of market actors and insufficient enforcement and control measures on the side of authorities.

(146) This notwithstanding, we further submit that with respect to Fluoropolymers any appropriate hazard assessment against the background of Article 57 REACH would have demonstrated that beyond the persistence no specific hazard properties can be identified for all Fluoropolymers in a way that would justify an identification as substances of very high concern or subsequent inclusion in Annex XIV. Therefore, an authorisation approach would have resulted in a regulatory approach excluding Fluoropolymers and, thus, would have been a less onerous approach for this subgroup of PFAS.

(147) And even if the Dossier Submitters would have considered less onerous options only within the framework of a restriction under REACH, it would have been appropriate to

provide for an initially unlimited exemption for Fluoropolymers because there are at least uncertainties regarding the hazard and risk profile and, if considered necessary by the Dossier Submitters, to link this to a mechanism a review period for the Commission to assess whether and to what extent specific properties have been identified. Although there is no sufficient basis for such further review according to the information presented in the Proposal, such approach would qualify as a less onerous measure and a well-established approach in connection with multiple other restrictions.

(148) In addition, such approach would also have supported any further assessment of specific uses and related alternatives. As far as an assessment of certain uses is not possible in connection with the decision on the Proposal, it would be possible to establish a review period for the Commission to assess whether suitable alternatives are available. In this respect, stakeholders would also have sufficient pressure to develop alternatives. However, it would not come to the scenario that the development of alternatives actually fails and thus, under certain circumstances, entire supply chains or industrial sectors are massively and possibly permanently disrupted by a certain deadline.

(149) It is true that the Commission could subsequently amend the text of the restriction and thus react to this situation. However, experience shows that the Commission has not made use of this possibility even in justified cases. Therefore, such approach cannot be considered as suitable alternative.

b) Inappropriate assessment of the alternatives available

(150) The dossier breaches the principle of proportionality for another reason, as it makes an inappropriate assessment of the alternatives available.

(151) The wording of Article 68(1) REACH already requires that a decision on a restriction has to take the availability of alternatives into account. Accordingly, Section 3 of Annex XV to REACH states that available information on alternative substances and techniques shall be provided, including information on the risks to human health and the environment related to the manufacture or use of the alternatives, availability (including the time scale) and technical and economic feasibility. The Guidance for the preparation of an Annex XV dossier for restrictions specifies these requirements and states that the respective aim is to provide information for the analysis of whether the equivalent function provided by the substance can be obtained by other substances or techniques (cf. Guidance, p. 68).

(152) Furthermore, according to the guidance document, an alternative shall mean alternative chemical substances or alternative techniques (processes and technologies) or combinations thereof that can be used to replace (partially or totally) the substance of concern in a given use or a number of uses by providing the equivalent function that the substance delivers in those uses or by making the function redundant (cf. Guidance, p. 69).

(153) Moreover, the information on alternatives should be used to "defining a proportionate restriction that is targeted to the identified risk" (cf. Guidance, p. 68) and in developing the justification that the proposed restriction is the most appropriate measure (cf. Guidance, p. 69). Thus, the guidance document clearly states, that the evaluation of alternatives is a necessary and mandatory part of a proportionate restriction proposal.

(154) In the present case, the assessment of available and, above all, future alternatives suffers from a decisive logical error. As can be seen in many passages, the assessment focuses on other substances that can have an equivalent function to PFAS. In this respect, the dossier adheres to the requirements of the guidance document, which specifies this as the definition of an alternative. However, the dossier fails to recognize that the decisive function of Fluoropolymers is precisely their persistence or their ability to persist in challenging environments like extremely high temperatures, inertness to highly reactive chemicals. Persistency in adverse environment is also the function of reliability or durability which is a requirement of many applications in particular aerospace, semiconductor, chemical process industry etc. In this respect, the dossier states in some passages that the common property of Fluoropolymers is their persistence and the dossier justifies the proposed restriction mainly with the fact that the substances are persistent. Other properties therefore play an additional role at best (cf., for example, Proposal, p. 22).

(155) Against this background, it contradicts any logic of thought that alternatives are sought which possess the same decisive property, because according to the logic of the dossier, the alternatives would not be allowed at all and would consequently have to be restricted. In this respect, the analysis of existing and future alternatives should necessarily revolve around alternatives of use and not around alternatives of substance.

(156) To that end, however, it needs to be submitted that, in general, no alternatives for Fluoropolymers are available. In addition, it is evident that for many applications there are no non-persistent alternatives available because Fluoropolymers are used precisely because of their unique properties, including persistence. This is especially true against the background that the Dossier Submitters want to prevent a "regrettable substitution". This consideration, however, is led ad absurdum if there is inevitably nothing that can be used as a suitable alternative. Consequently, persistent alternatives are not to be considered in the present case. Thus, on the one hand, there is a major error in the information about the alternatives, which makes the dossier disproportionate. On the other hand, the dossier is already disproportionate in general because it contains alternatives which are under scrutiny according to the logic of the dossier due to their persistence.

5. Infringement of the principle of good administration

(157) The Dossier also infringes the principle of good administration due to further inconsistencies. The principle is codified in Article 41 of the Charter of Fundamental Rights of the European Union, the Rules of Procedure of the Commission and the European Code of

Good Administrative Behaviour. The principle comprises the general principle that authorities need to be consistent in their administrative behaviour and shall follow their normal practice, with the effect that legitimate expectations of the public are met.

(158) A deficiency of the procedure results from the fact that, according to the dossier, the stakeholders are supposed to prove that specific PFAS are not hazardous or persistent (cf. Proposal, Annex B, page 3). This is the consequence of the group-based approach, by which a large number of individual substances are to be covered by the restriction, although for the vast majority of the substances no studies or evidence with regard to their hazard properties are available.

(159) However, such a procedure violates the procedural rules for a restriction procedure under REACH with regard to the burden of proof. Articles 68 et seqq. REACH do not state at any point that the stakeholders, i.e. affected market actors, must provide evidence of the non-hazardousness of a particular substance. The hazard assessment described in the corresponding guidance document also explicitly provides only for such an assessment by the Dossier Submitters and not by the stakeholders (cf. Guidance, p. 34 et seqq.). Thus, in the context of the PFAS restriction, the German competent authority (BAuA) also stated that in the case of restriction, the burden of proof lies with the authority and, in contrast, in the case of authorization, the burden of proof lies with the industry (cf. BAuA webinar of 3 April 2023, presentation by Dr. Herkert, slide 5). By leaving concrete evidence with regard to the non-hazardousness of a concrete substance to industry, the present restriction procedure acts contrary to the applicable burden of proof rules.

(160) This is particularly unacceptable in view of the fact that the individual stakeholders - contrary to the Dossier Submitters - cannot opt for a group-based approach because they only use one or a few of the substances and thus have information on them. It is almost audacious that the Dossier Submitters admit that for many substances there is a lack of concrete scientific evidence for a hazardous property, but at the same time demand evidence for non-hazardousness from the stakeholders in connection with requests for exemptions or derogations.

(161) Incidentally, it should be noted that the consultation process does not affect these considerations. It is true that the stakeholders have the opportunity to make a submission on the hazardousness or non-hazardousness of certain substances. However, they are not obliged to do so, so that the de facto reversal of the burden of proof is fully at their expense if they do not participate in the consultation procedure.

(162) We further submit that the approach also infringes procedural rights of affected market actors. If the authorities would have chosen an authorisation process, affected market actors would have been in the position to prepare an application for authorisation typically within a time period of 18 to 24 months after inclusion of substances in Annex XIV to REACH. In connection with the determination of the respective last application date

(cf. Article 58(1)(c)(ii) REACH) a broad variety of factors need to be considered as established with the corresponding ECHA Practical Implementation document on Setting Latest Application Dates (cf. https://echa.europa.eu/documents/10162/17232/recom_gen_approach_draft_axiv_entries_impl_doc_2020_en.pdf). It follows already from the details set out in this document that a complex ban as supported with the Proposal would have resulted in a time period of 24 months after inclusion of substances in Annex XIV to REACH to set the last application date.

(163) By illicitly initiating a restriction proceeding under Titel VIII of REACH, the time period for affected market actors to create convincing submissions to request and justify exemptions or derogations, including supporting data on alternatives, environmental fate and socio-economic considerations as requested in connection with the public consultation, is significantly shortened to roughly six months, i.e. the duration of the public consultation according to Article 69(6) REACH.

(164) The burdens associated with this are also not compensated by the fact that the restriction proposal was already under discussion beforehand and affected actors could thus have prepared themselves at an early stage. It needs to be noted that the actual restriction proposal was initially published only on 7 February 2023 and the version currently subject of the public consultation was in fact only published on 22 March 2023, i.e. the date on which the public consultation was initiated.

6. Breach of precautionary principle

(165) The Proposal does not align with the precautionary principle but has an arbitrary nature.

(166) According to Article 191(2) TFEU, every REACH measure aiming at a Union policy on the environment has to take into account the precautionary principle. In contrary, such measures shall not be of an arbitrary nature. There is no definition for the precautionary principle in the EU treaties, but the Commission and case law have specified the content.

(167) As already stated (cf. paragraph (67) above) the Commission has laid down its interpretation of the principle in a separate communication on the precautionary principle (cf. COM(2000) 1 final, dated 2 February 2000). According to this, the determination of appropriate action including measures based on the precautionary principle should start with a scientific evaluation to perform an as objective and complete as possible scientific evaluation to cast light on the existing objective evidence, the gaps in knowledge and the scientific uncertainties (cf. ibid, p. 16). In particular, the precautionary principle can under no circumstances be used to justify the adoption of arbitrary decisions (cf. ibid, p. 13). This requires reliable scientific data and logical reasoning, leading to a conclusion which expresses the possibility of occurrence and the severity of a hazard's impact (cf. ibid, p. 13). The limits of scientific knowledge may ultimately affect the foundation for protective or preventive action (ibid, p. 13). Particularly, this applies for the scenario, that scientific data are not sufficient and therefore cause-effect relationships are suspected

but have not been demonstrated (cf. ibid, p. 14). Furthermore, according to the Commission, the measures based on the precautionary principle must not be disproportionate to the desired level of protection and must not aim at zero risk (cf. ibid, p. 17). Accordingly, in some cases a total ban may not be a proportional response to a potential risk (cf. ibid, p. 17).

(168) According to the ECJ, the precautionary principle entails that, where there is uncertainty as to the existence or extent of risks to human health, protective measures may be taken without having to wait until the reality and seriousness of those risks become fully apparent. Where it proves to be impossible to determine with certainty the existence or extent of the alleged risk because the results of studies conducted are inconclusive, but the likelihood of real harm to public health persists should the risk materialise, the precautionary principle justifies the adoption of restrictive measures (Judgement of 1 October 2019, Case C-616/17, ECLI:EU: C:2019:800, para. 43.). However, a correct application of that principle presupposes, first, identification of the potentially negative consequences for health of the proposed use of the substance at issue, and, secondly, a comprehensive assessment of the risk to health based on the most reliable scientific data available and the most recent results of international research (Judgement of 4 April 2019, Case T-108/17, ECLI:EU:T:2019:215, para. 281).

(169) Measured against these criteria, the implementation of a general ban on (almost) all known and even currently unknown PFAS after the expiry of certain transitional periods, as proposed by the Dossier Submitters, would violate the precautionary principle, since it would be based to a large extent on a mere risk hypothesis and not on scientifically substantiated risk assessment. If the Commission were to follow the proposal, it would violate its self-imposed principles, according to which a restrictive measure may not be taken on the basis of the principle of general precaution alone, in order to limit a potential risk to zero, without any comprehensible, scientific evidence for this in detail.

(170) There are numerous examples of such violations in the dossier. The group-based approach applied by the Dossier Submitters already raises fundamental concerns with regard to the precautionary principle (cf. Proposal, p. 21). Such an approach does not allow the exact determination of the possible risks of a certain substance, but is only able to draw conclusions, which cannot be scientifically justified in detail, from possible risks of certain substances belonging to a group to other substances of this group which have not been investigated.

(171) By seeking to prevent substitutions with other PFAS, the Dossier Submitters are abandoning the principle of precaution and are pursuing a risk minimization to zero, which in fact is neither needed with regard to the precautionary principle, nor can it be justified by a mere reference to this principle.

(172) Furthermore, the Dossier Submitters are not able to present logically comprehensible, scientifically based prediction tools for possible negative effects of Fluoropolymers in the

environment (cf. Proposal, p. 37). A substantiated risk assessment is not possible in this way; rather, the approach contradicts the requirements linked to the application of the precautionary principle as established by both, the Commission and the ECJ, according to which restrictions may only be made on the basis of a risk assessment based on the most reliable scientific data available and the latest results of international research, and not merely on a purely hypothetical risk assessment based on mere conjecture that has not yet been scientifically verified.

(173) Although, as shown, for many PFAS except Fluoropolymers, there are no or only few scientific studies available with regard to their possible hazardousness, the dossier does not provide for the possibility of extending the maximum possible 13,5-year derogation if no alternative substances have been found within this period of time. Nor does the dossier take into account the fact that future studies could disprove or at least relativize the hazards of Fluoropolymers assumed by the dossier authors. The correct application of the precautionary principle, however, requires a consideration of such possibilities. Moreover, for Fluoropolymers available data already supports a non-time-limited derogation which is also not sufficiently reflected in the Proposal.

(174) Further examples of violations of the precautionary principle can be found in Annex B. With regard to risk assessment, for example, it is described that a decreasing trend can be seen in humans, but in creatures the trends were inconsistent and (only) in some cases increasing (Annex B p. 97). However, the studies refer to PFSA and PFCA and precisely not to all PFAS and especially not to Fluoropolymers. The same applies, for example, to the immunological analysis, in which conclusions are drawn for all PFAS on the basis of studies on only specific PFAS without further justification (Annex B, p. 181). In this respect, the principle of caution is applied and not the precautionary principle as established by the Commission and the ECJ. In particular, there is an approach to achieve zero risk, which, as explained above, does not correspond to the precautionary principle.

7. Infringement of right to be heard / right to comment

(175) The dossier infringes the stakeholders` right to be heard and right to comment. This follows from the fact that the proposed measure is, in effect, an authorization in the guise of a restriction.

(176) In fact, the initial situation and the circumstances of the PFAS case strongly imply that the Dossier Submitters should rather have sought an authorization procedure. By failing to do so, they curtailed the participation rights and procedural rights enshrined in Article 59 REACH. In addition, if stakeholders were required to seek authorization, they would have a regulated process (namely, the authorization process) open to them in which they could argue socio-economically for certain uses in a regulated process. In contrast, the restriction process does not provide for mandatory participation; moreover, in contrast to the - necessarily individual - authorization decision, there is also no obligation

on the part of the authorities to deal with the specific use and to make an individual, judicially reviewable decision in the specific case.

(177) The objective circumstances correspond to those of a potential authorization procedure. This is evident in particular from the fact that the Dossier Submitters obviously largely lack information on the concrete uses of the substances. After all, they themselves state that there are further uses not addressed in the dossier (cf. Information note on restriction report, Consultation on a proposed restriction on the manufacture, placing on the market and use of per- and polyfluoroalkyl substances (PFAS), p. 5).

(178) Moreover, there is obviously only a rather low level of knowledge regarding the socio-economic consideration. In particular, information on existing and future alternatives is largely lacking, which is now to be provided by stakeholders within the framework of the consultation procedure, as is already evident from the structure and content of the corresponding ECHA webform (cf. Information note on restriction report, Consultation on a proposed restriction on the manufacture, placing on the market and use of per- and polyfluoroalkyl substances (PFAS), p. 5).

(179) This applies above all to Fluoropolymers. For this subgroup the level of knowledge is apparently so low that for them - in contrast to the other PFAS - it is even included in the proposed entry text of the restriction proposal (cf. Proposal No. 8) that (for the use of derogations already provided for) a management plan must be drawn up, from which, among other things, information on the substance and the product and a justification for the use must be provided.

(180) However, it is precisely this initial situation that requires the issuance of an authorization procedure. After all, authorization and restriction must be differentiated on the basis of the fact that the burden of proof, especially for exemptions, lies with the authority for the restriction and precisely not for the authorization. If the authorities have so little information, particularly in the socio-economic dimension, as in the present case, this system dictates to consider an authorization and that the stakeholders should therefore have the opportunity to obtain exemptions in an orderly procedure. They were deprived of these rights due to the choice of the wrong measure, so that the participation and procedural rights were and are violated.

III. Reference to other parts of the submission

(181) As shown in detail above, the proposal is entirely insufficient from a legal point of view with regard to Fluoropolymers. As demonstrated above, the requirements of Article 68 REACH have not been met, in particular because, contrary to all known systematics and dogmatics, persistence was considered to be the key hazardous property. In addition, various superior legal principles were violated, in particular the principle of proportionality and the precautionary principle.

(182) Following on from this conclusion, it should be noted, that the Proposal cannot provide a detailed socio-economic consideration and an assessment of the exposure and hazard of the PFAS in question for all uses of PFAS. This can already be seen from the fact that the Dossier Submitters - as ECHA admits, cf. e.g. No. 6 of the Specific Information Requests - do not have knowledge of all use cases of PFAS and therefore could not include them in the Proposal.

(183) Especially, regarding the socio-economic analysis, the Dossier Submitters seem to lack in particular an estimation of the expected costs of a possible replacement of products, including the immediate phase-out of products. Only with the help of such data, however, is it possible to conclude how this relates to, for example, the expected environmental impact costs.

(184) Moreover, the Dossier Submitters did not conduct a hazard and risk assessment for each PFAS and not even for each PFAS group. This unlawful grouping results in the consequence that it is up to the stakeholders to contribute various information for their respective product or use and for the corresponding PFAS. In this respect, ECHA's webform on the consultation process and the corresponding guidance reveal that information is missing and what data should be provided by stakeholders for both known uses and as yet unknown uses.

(185) Against this background, GFL submits further information as part of its broader submission. From a legal perspective, these additional studies, reports and papers precisely support the legal assessment at hand. In particular, the breach of the principle of proportionality, the breach of the precautionary principle and the conclusion, that the proposal fails to provide a sufficient socio-economic analysis for each substance concerned arise already from these papers.

IV. Conclusion

(186) Against the background of the aforementioned arguments, a general exemption or derogation without any time limit for Fluoropolymers is warranted. Without a corresponding exemption or derogation, a restriction, if adopted, would constitute infringements of the prerequisites as set out in the REACH Regulation as well as fundamental principles enshrined in the European Union Charter of Fundamental Rights. We therefore suggest incorporating a corresponding section in the potential REACH Annex XVII entry regarding PFAS:

> **"Paragraph 1 and 2 shall not apply to Fluoropolymers. This derogation does not apply to PFAS used as polymerisation aids for the production of Fluoropolymers."**

(187) In addition, the Proposal should be amended accordingly to ensure that no additional provisions as proposed with Nos. 5 a), 6, 7 and 8 of the contemplated entry to Annex XVII to REACH contradict the aforementioned derogation.

(188) Therefore, we respectfully request ECHA, RAC, SEAC and the Dossier Submitters to consider the concerns raised with this submission and the further arguments as brought forward and supported by the broader submission of GFL to avoid procedural shortcomings which might give rise to further legal concerns.

Augsburg, 21 June 2023

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