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APPENDIX

3M COMMENTS ON THE PROPOSED
UNIVERSAL PFAS RESTRICTION UNDER EU REACH

To Whom It May Concern:

The 3M Company (3M) appreciates the opportunity to provide comments on the Annex XV Restriction proposal to restriction the manufacture, placing on the market and use of per- and polyfluoroalkyl substances (PFAS) (the "Proposed Restriction").

3M is a science-based company committed to responsible innovation. 3M supports the proactive management of PFAS and the goal of using science-based regulatory standards to address PFAS in the environment. We have and will continue to work with stakeholders to help support reasonable, science-based regulations and policies that address PFAS use and management as we implement our previously announced decision to exit all PFAS manufacturing by the end of 2025 and work to eliminate the use of PFAS across our product portfolio.

It is with that background in mind that 3M offers the following comments on the Proposed Restriction.

I. EXECUTIVE SUMMARY

Article 68 of REACH requires that regulators establish an "unacceptable risk" before banning or restricting a chemical substance. The Proposed Restriction fails to do that here. As discussed below, the Proposed Restriction impermissibly attempts to ban thousands of substances based on a purported finding that ***some*** of those substances ***may*** present an unacceptable risk, in violation of the REACH Regulation.

The Proposed Restriction also does not properly follow the science-based guidance documents and frameworks that govern the implementation and evidence-based execution of REACH. Rather, it improperly attempts to group and restrict thousands of substances and subgroups of fluorinated chemistries that have significantly varied physical, chemical and biological properties.

More specifically:

The Proposed Restriction adopts the broad OECD definition of PFAS and, in so doing, attempts to treat thousands of substances with varying properties as presenting the same risks, even though the actual risks associated with the majority of those substances have not been evaluated. This approach contradicts both the plain language of REACH and ECHA's guidance.

The Proposed Restriction appears to find "unacceptable risk" based largely on the fact that the chemical structure of the broad group of PFAS renders them "persistent." This approach ignores the EU legislator's position that persistence, alone, cannot establish "unacceptable risk" warranting a restriction under REACH.

To the extent the Proposed Restriction considers risk *other than* persistence, it improperly assumes that the hazardous properties of a few PFAS can be imputed to the entire class of PFAS.

The risk analysis that is included in the Proposed Restriction and supporting documents were not conducted in accordance with applicable guidance and best practices for determining "unacceptable risk." While REACH does allow for regulators to follow a "read-across" approach in certain circumstances – wherein chemicals within the same class are restricted on the basis of their common characteristics – that approach appears to not be properly followed here. As will be discussed herein, the scientific evidence demonstrates, and numerous experts agree, that it is inappropriate to assume equal toxicity/potency across the diverse class of PFAS for purposes of human health risk and environmental risk assessment.[1] In other words, the purported structural similarity of various PFAS substances does not support adding all PFAS to one group for risk assessment purposes.[2]

Finally, the Proposed Restriction improperly rests upon uncertain emissions estimates that do not take into consideration recent advancements in control and treatment technologies or the regulatory framework applicable to operations in EU Member States.

As a result of the deficiencies discussed herein, the Proposed Restriction does not reflect an appropriate and science-based regulatory approach.

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[1] *See, e.g.*, Anderson et al., 2022; Antoniou et al., 2022; Colnot and Dekant 2022; Goodrum et al. 2021; Peters and Gonzalez, 2011; SCHEER, 2022; Scialli et al. 2007, as quoted in the References appendix to these comments.
As demonstrated below, the Proposed Restriction inappropriately adopts the OECD definition of PFAS for regulatory purposes and attempts to restrict all of the thousands of chemistries that fall within it, even while acknowledging that regulators have not assessed any actual risks posed by the vast majority of those chemistries. The resulting restriction impermissibly considers only chemical structure and not specific hazards or risks that differing PFAS chemistries might present. The OECD itself counsels against such an approach in its report "Reconciling Terminology of the Universe of Per- and Polyfluoroalkyl Substances: Recommendations and Practical Guidance", July 2021, (the "**OECD Report**"). This approach also contradicts ECHA's own guidance documents for assessing chemical hazards and risk (ECHA IR&CSA, Part E (2016), Chapter R.11 (2017), Part D (2016); ECHA (2018) Guidance on the Preparation of an Annex XV Dossier for the Identification of SVHC).

2 This lack of sufficient evidence for most PFAS also means that a general Restriction as proposed is not justifiable. For PFHxA, for example, the limitations of the Annex XV Dossier in terms of missing or uncertain or unreliable data on emission, risk reduction and socio-economic impacts – as noted by the Commission, RAC and SEAC – led to a "targeted" restriction of only applications for which it is not possible to implement risk management measures to minimize emissions and for which a restriction is likely appropriate (or not inappropriate) in terms of socio-economic benefits and costs. The Proposed Restriction has even more data gaps and weakness than the PFHxA restriction and should lead EU authorities to limit that restriction to those applications *"where it is not possible to implement risk management measures to minimize emissions"* (*see* ECHA's RAC and SEAC Opinion on Annex XV dossier on the restriction of undecafluorohexanoic acid (PFHxA), its salts and related substances, p. 9) and where *"restricting that specific use is (as a minimum) likely appropriate or likely not inappropriate in terms of socio-economic benefits and costs."* (Draft Commission Regulation amending Annex XVII to REACH as regards PFHxA, its salts and PFHxA-related substances, Recital 14). Any other approach would be inconsistent and discriminatory.

II. THE PROPOSED RESTRICTION ATTEMPTS TO RESTRICT AN OVERLY BROAD CLASS OF "PFAS"

A. The OECD Definition is Not Appropriate for Regulatory Purposes

The Proposed Restriction employs a broad, structure-based definition of PFAS derived from the OECD Report[3] "Reconciling Terminology of the Universe of Per- and Polyfluoroalkyl Substances: Recommendations and Practical Guidance" (the "OECD Report"). However, OECD itself acknowledges that "the term 'PFAS' used therein is a broad, general, non-specific term, which "*does not inform whether a compound is harmful or not* (emphasis added), but only communicates that the compounds under this term share the same structural trait of having a fully fluorinated methyl or methylene carbon moiety"[4].

OECD further highlights that, among the substances defined as PFAS, there are many distinct substances with very different properties and diverse molecular structures that result in diverse physical, chemical, and biological properties (with differences in, for example, volatility, solubility, reactivity, etc.). The broad chemical class ranges from gases to liquids to solids, some of which are chemically and biologically inert and present little potential for human exposure. These distinct and diverse properties bear directly on the assessment of risk for each individual substance. For example, this broad range would cover fluorinated compounds from tetrafluoromethane (an industrially used gas) to polytetrafluoroethylene (a solid polymer), neither of which presents meaningful opportunity for human exposure, potential for bioaccumulation or exhibits any measurable toxicity[5].

Accordingly, the OECD Report recommends that such diversity be properly recognized, and notes that its decision to use a broad definition is "not connected to decisions on how PFAS should be grouped in regulatory and voluntary actions"[6]. Instead, as other experts have acknowledged, "*regulatory definitions (subgroupings) of PFAS will need to be devised for individual regulatory purposes*" (emphasis added)[7]. The EU Scientific Committee on Health, Environmental and Emerging Risks (SCHEER), in its opinion report, also agreed that the PFAS definition or "group" needs to be fit-for-purpose and that the OECD 2021 definition should be refined for specific risk assessment goals[8].

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[3] OECD Report, p. 18
The Proposed Restriction includes an exception to this definition. "The exception concerns certain fully degradable PFASs subgroups that only contain some specific structural elements. A substance that only contains the following structural elements is excluded from the scope of the proposed restriction:

- CF_3-X or X-CF_2-X', where X = -OR or –NRR' and
- X' = methyl (-CH_3), methylene (-CH_2-), an aromatic group, a carbonyl group (-C(O)-), -OR'', -SR'' or -NR''R''';

And where R/R'/R''/R''' is a hydrogen (-H), methyl (-CH_3), methylene (-CH_2-), an aromatic group or a carbonyl group (-C(O)-)." (p. 14)

[4] OECD Report, p. 8.
[5] Ibid.
[6] Ibid.
[7] Anderson et al. 2022, as quoted in the References appendix to these comments, p. 4.
[8] SCHEER 2022, as quoted in the References appendix to these comments.

In short, and as discussed further below, basing the scope of the Proposed Restriction on OECD's broad definition, which refers only to the chemical structure of PFAS, does not consider the distinct properties, hazards and risks of the different PFAS subgroups and individual substances, violates the requirements of REACH.

B. There Has Been No Showing of Unacceptable Risk for PFAS As a Class

Absent a valid risk assessment that encompasses all PFAS substances (discussed *infra*), the Proposed Restriction's adoption of the broad OECD definition of PFAS for regulatory purposes contradicts both the plain language of REACH and ECHA's own guidance. Articles 68(1) and 69(1) and Section II.3 of Annex XV to REACH require "an assessment of the hazard and risks according to the relevant parts of Annex I." Therefore, the Proposed Restriction must identify and describe the hazard(s) of each substance in line with the relevant provisions of the Classification, Labeling and Packaging (CLP) Regulation and/or conduct a PBT/vPvB assessment per Annex XIII of REACH. It must then demonstrate that there "is" an unacceptable risk, when accounting for the exposure assessment and risk characterization per Annex I. This process has not been conducted for the vast majority of PFAS substances covered in the Proposed Restriction. Accordingly, no demonstration of acceptable risk has been made.

The Proposed Restriction acknowledges that there are data gaps and widely heterogeneous physical-chemical properties and toxicities across PFAS compounds. For example, the Proposed Restriction (Annex B) notes that properties such as water solubility, adsorption potential, bioaccumulation potential, and half-life vary across PFAS and there are only a few toxicity studies for some subclasses of PFAS (e.g., polymeric PFAS). Despite these admitted facts, the Proposed Restriction does not follow ECHA's guidance to assess data gaps where appropriate[9]. Most critically, the Proposed Restriction also does not acknowledge that this heterogeneity in properties and toxicities prevents meaningful assessment of PFAS hazards and risks across a broad grouping of compounds.

The Proposed Restriction also does not follow the criteria for grouping as set forth in Annex XI of REACH and in ECHA's own Read-Across Assessment Framework ("RAAF") Guidance[10]. Section 1.5 of Annex XI to REACH provides the rules applicable to the grouping of substances and a read-across approach for registration purposes. In particular, a grouping of substances is limited to "*(s)ubstances whose physicochemical, toxicological and ecotoxicological properties are likely to be similar or follow a regular pattern as a result of structural similarity*" (emphasis added). Structural similarity is therefore a necessary condition but is not sufficient on its own to justify a grouping since Section 1.5 further provides that "*(a)pplication of the group concept requires that physico-chemical properties, human health effects and environmental effects or environmental fate may be predicted from data for reference substance(s) within the group by interpolation to other substances in the group"* (emphasis added).

[9] ECHA IR&CSA.
[10] ECHA Read-Across Assessment Framework (RAAF), March 2017

ECHA has detailed further in its own RAAF Guidance the requirements for relying on a read-across approach. Per such Guidance "read-across involves the use of relevant information from analogous substance(s) (the 'source' information) to predict properties for the 'target' substance(s) under consideration"[11]. The Guidance notes that chemical groupings should ensure that the "prediction of a property based on read-across is reliable, can be used for risk assessment and/or classification and labelling, and complies in general with the provisions in REACH for the substance under consideration"[12]. By contrast, the Proposed Restriction does not identify any hazardous properties or risks common to all PFAS to support the grouping as a single class.[13] Furthermore, toxicity data developed by studying certain long-chain PFAS compounds (like perfluorooctane sulfonate [PFOS] and perfluorooctanoic acid [PFOA]) do not and cannot be applied to all PFAS because of significant differences among the compounds, which have widely varying characteristics.[14]

Differences in solubility is a simple example of the wide range of chemical characteristics of PFAS. Certain short-chain PFAS[15]may be water soluble in the milligram to gram per liter range, whereas longer-chain PFAS can have solubilities below 1 mg/L[16]. Given the vastly varying molecular structures and polarities of moieties, even a comparable water solubility among some PFAS would not imply identical properties. These properties can profoundly affect a substance's occurrence in aqueous media and air. The interplay and interdependence of these structural chemical and physical-chemical properties strongly influence the differences in toxicokinetics among PFAS. These differences among PFAS in physical-chemical properties, toxicokinetics, and toxicity can, in turn, directly affect bioaccumulation and risk to humans and the environment.[17]

Multiple expert panels and researchers have also acknowledged that not all PFAS share the same properties and that it is inappropriate to assume equal toxicity/potency across the diverse class of PFAS for human health risk or environmental safety and fate assessment, and that assessing potential risks of even a representative mixture of PFAS is complex[18]. The Proposed

[11] Ibid., p. 4.
[12] Ibid.
[13] As discussed *infra*, persistence, alone, does not support the broad restriction proposed here.
[14] Although Annex XI to the REACH Regulation foresees grouping and read-across as a possible means for registrants to adapt standard registration requirements, it must apply by analogy to authorities when they seek to group substances for regulatory purposes, including in the context of a REACH Restriction, and the same applies to the RAAF. Indeed, there is no reason for different rules to apply to registrants and authorities, as the objective of using grouping is the same. Also, there is no alternative approach set out in REACH that authorities could apply. This is because the EU legislator has foreseen grouping as a means to ensure that information requirements fit real information needs, and to condition a right to adaptation for registrants to specific clear rules and criteria. Furthermore, as stated by ECHA, "*(t)he RAAF provides a framework and guidance for consistent evaluation of the scientific aspects of a proposed read-across case, resulting in an output which is suitable for subsequent regulatory consideration of the read-across case*" (*see* ECHA RAAF, p. 4). Finally, it is essential that authorities apply clear, foreseeable and sound rules and criteria on the grouping of substances for risk management purposes, and in the absence of other guidance or criteria, only the rules of Annex XI and the RAAF provide the required level of clarity and foreseeability.
[15] Including perfluoroalkyl carboxylic acids (PFCAs) and their anions, perfluorinated sulfonic acids (PFSAs)and their sulfonates, and fluorotelomer carboxylic acids and carboxylates (FTCAs)
[16] https://pfas-1.itrcweb.org/wp-content/uploads/2022/01/ITRC_PFAS_PhysChemProp_Table_4-1_Oct2021.xlsx.
[17] For example, the steady-state body burden at constant exposure is generally higher for a substance with a longer terminal elimination half-life, and is generally lower if there is a larger volume of distribution, a key variable of physiological disposition (the volume of distribution) that is determined by structural chemical and physical-chemical properties of the material.
[18] Anderson et al. 2022; Antoniou et al. 2022; Colnot and Dekant 2022; Goodrum et al. 2021; Peters and Gonzalez 2011; SCHEER 2022; Scialli et al. 2007, as quoted in the References appendix to these comments.

Restriction does not appear to consider these publications, and thus, it fails to acknowledge that from a scientific point of view, it has not been shown that the purported structural similarity of various PFAS substances supports assessment of risks posed by PFAS as a class.[19]

C. An Assumption of Persistence Does Not Demonstrate Unacceptable Risk Under REACH

The Proposed Restriction relies on the alleged persistence of all PFAS to justify its requirements. As it does not demonstrate any other effects for all PFAS (it actually acknowledges the differences in other properties), the Proposed Restriction is *de facto* based only on a persistence concern. However, even assuming that all PFAS are, in fact, persistent, *quod non*, there is no basis in REACH or in the CLP Regulation for the conclusion that persistence, alone, represents an "unacceptable risk" that can serve as the basis for such a wholesale restriction.

1. REACH Does Not Permit the Restriction of Thousands of Substances on the Basis of Persistence Alone

There is no language in REACH supporting the notion that persistence alone justifies risk management measures. To the contrary, REACH combines persistence with bioaccumulation and toxicity to justify designation as a substance of very high concern (SVHC), demonstrating that REACH does not see persistence alone as justifying risk management measures. Moreover, the recently adopted Commission Delegated Regulation 2023/707 amends the CLP Regulation with the PBT and vPvB criteria, mirroring the REACH Annex XIII criteria, and establishing the new PMT (Persistent, Mobile and Toxic) and vPvM (Very Persistent and Very Mobile) hazard categories[20]. Importantly, the EU legislator did not identify the persistence criteria as a standalone hazard category when recently amending the CLP Regulation.

ECHA's own guidance confirms that, for persistence to be a criterion upon which to regulate a substance with limited data, weight of evidence for other properties such as bioaccumulation and/or toxicity must be provided before persistence alone can be considered a risk factor[21]. In Case C-558/21,[22] Advocate General Kokott points out that even for substances that are demonstrated persistent, bioaccumulative and toxic (PBT) or very persistent and very

[19] Regulators acknowledge that even more widely studied PFAS can pose varying levels of risk. For example, the U.S. EPA has set a health advisory level – the level which the Agency states "identif[ies] the concentration of chemicals in drinking water at or below which adverse health effects are not anticipated to occur" for HFPO-DA at 10 ppt in drinking water and for PFBS at 2,000 ppt – more than 200 times higher.

[20] European Commission, Delegated Regulation (EU) 2023/707 of 19 December 2022 amending Regulation (EC) No 1272/2008 as regards hazard classes and criteria for the classification, labelling and packaging of substances and mixtures (OJ L 93/7, 31.3.2023).

[21] ECHA IR&CSA, Chapter R.11: PBT/vPvB assessment, Version 3.0, p. 15, 35.

[22] Opinion of Advocate General Kokott delivered on 20 April 2023 in Case C-558/21, ECLI:EU:C:2023:320, (para. 89), which is hearing an appeal against the General Court Ruling in Case T-226/18, also referred to in these comments, which relates to the EU Restriction on D4-D5.

bioaccumulative (vPvB), "the REACH Regulation does not require that any release of (PBT/vPvB substances) be prevented".[23]

The Proposed Restriction is using the same approach as the one followed for PBT/vPvB in Case T-226/18 because the concern for PFAS is allegedly similar to those of the PBT/vPvB substances in that case. In particular, it acknowledges that the purported (v)P is not sufficient to identify PFAS as PBT/vPvB and that "*no overall conclusion on B/vB and T criteria was derived for each PFAS substance/(sub-)group"*[24]. The Proposed Restriction nevertheless considers that the overall concern for PFAS is similar to that for PBT/vPvB substances because of their purported "additional properties" combined with the alleged (v)P property. This is neither justified nor corroborated.

First, the "additional properties" described in the Annex XV Report of the Proposed Restriction have not been shown to apply to *all* PFAS proposed to be restricted. Each PFAS substance/(sub-)group has distinct properties and a distinct hazard profile. They should therefore be separately assessed to conclude whether they raise concerns similar to that of PBT/vPvB substances. The Proposed Restriction does not do that, instead it assumes that any property of any individual PFAS substance in combination with (v)P raises a similar concern to that of PBT/vPvBs for all PFASs.

Second, even if the European Courts in Case T-226/18 have ruled that emission of substances identified as PBT/vPvB as per the criteria of Annex XIII of REACH can be considered as a proxy for (an unacceptable) risk, there is nothing in the case law or applicable legislation that allows extrapolating such conclusion for substances that are not PBT/vPvB, including PFASs that present only persistent or very persistent properties. As explained by the Advocate General Kokott in her Opinion in Case C-558/21 P[25], it is because of the specific language of point 4.0.1 of Annex I to the REACH Regulation that is specific to substances meeting the PBT/vPvB criteria of Annex XIII of the REACH Regulation that there is no need to define an acceptable risk for such substances. In particular, according to point 4.0.1 of Annex I to REACH, a hazard and exposure assessment as carried out for other substances in accordance with Sections 1 and 3 of Annex I cannot be carried out with sufficient reliability for PBT/vPvB substances. The same cannot be said for substances that only have P or vP properties. For substances that are not identified as PBT/vPvB, such as many PFAS, the risk assessment described in Annex I, comprising a human

[23] The Dossier Submitters seem to rely on the General Court's ruling in Case T-226/18, the so-called *Global Silicones* case. That case concerned specifically the restriction of PBT/vPvB substances (D4 and D5) identified in accordance with the criteria in Annex XIII REACH. The Court held that for the restriction of such substances there is no need to define a threshold of acceptable risk, below which releases are allowed, because the risks associated with PBT/vPvB cannot be addressed with sufficient reliability and in a qualitative manner. According to the Court – and as confirmed by Advocate General Kokott – this follows from the specific risk assessment rules for such substances laid down in point 4.0.1 of Annex I to REACH. (*see* Judgement of the General Court of 30 June 2021, Case T-226/18 *Global Silicones Council and Others v Commission*, para 191.) This ruling is now under appeal in Case C-558/21, in the context of which the Advocate General (AG) Kokott recently issued an Opinion that provides useful explanations of the General Court's judgement and clarifies the concepts of "emissions as a proxy for (unacceptable) risk" and the application of the precautionary principle.

[24] Proposed Restriction, p. 47.

[25] Opinion of Advocate General Kokott in Case C-558/21, para. 75.

health and environmental hazard assessment, an exposure assessment and a risk characterization, must be conducted.

As interpreted, the rationale for the risks presented by PBT/vPvB substances is their potential to accumulate in the environment which accumulation is difficult to reverse (para 2). However, as specified in the Annex XV Report of the Proposed Restriction, "*for the majority of PFAS no, or insufficient, data on bioaccumulation behaviour are available"* and therefore that the *"data on the bioaccumulation potential of PFAS [..] are not sufficient to substantiate bioaccumulation in the environment for all PFAS*"[26]. With respect to ecotoxicity, it mentions that "*the large number of different substances with heterogenous properties […] in the group of PFAS makes the assessment of their ecotoxicity very complex*"[27]. The Proposed Restriction then concludes that the bioaccumulation potential and (eco)toxicity is expected to vary among PFAS due to their "*high diversity*" and that "*no overall conclusion on B/vB and T criteria was derived for each PFAS substance/ (sub-) group*"[28]. Accordingly, even if the conclusions for PBT/vPvB substances could be applied to PFAS on the basis of their potential to accumulate – *quod non* as demonstrated above – this has not been demonstrated for all PFAS. Therefore, even adopting the rationale of the court in Case C-558/21 would not justify the restriction proposed here.

Third, "*the REACH Regulation does not require that any release of (PBT/vPvB substances) be prevented*"[29]. For AG Kokott, the restriction of the PBT/vPvB substances at issue (D4 and D5) "*is not based on the idea that any release of PBT/vPvB substances require a restriction. The reason for the restriction is, instead, that the substances at issue should be prevented from being released into the aquatic environment as a result of their use in wash-off cosmetics*"[30]. As AG Kokott puts it, the restriction addresses a "specific risk"[31] (in the case at issue the release into the aquatic environment because of their use in wash-off cosmetic products) and not any release of the substance. Therefore, if even for identified PBT/vPvBs, the REACH Regulation does not require that all releases be prevented, the same must hold even more true for PFASs that are not PBT/vPvBs.

Contrary to the AG Kokott's Opinion, the Proposed Restriction appears to be based on the premise that any release of any PFAS substance is a proxy for unacceptable risk[32]. On those grounds, the Proposed Restriction foresees a general ban on all PFAS for all uses (with some derogations/exemptions) to address a "concern" and not even "specific" identified risks. At a minimum, a full proportionality analysis is needed, substance by substance and application by application, to identify if the proposed restriction is appropriate, necessary and the least onerous measure for the aim pursued.

[26] Proposed Restriction, p. 28.
[27] Ibid.
[28] Ibid., p. 47.
[29] Opinion of Advocate General Kokott in Case C-558/21, para. 89.
[30] Ibid, para. 91.
[31] Ibid., para. 92, 100.
[32] Proposed Restriction, pp. 50, 190.

As AG Kokott puts it, "there may be several substances posing identical risks which offer advantages with different degrees of significance"[33]. That is why it is "conceivable" for the same risk to be regarded as acceptable for a very advantageous substance, but not for a less advantageous substance[34]. It follows that the Proposed Restriction cannot assume that any release of any PFAS and in any use is automatically a proxy for "unacceptable" risk, and therefore justifies being restricted.

2. REACH Does Not Permit the Restriction of Thousands of Substances on the Basis of a "Concern" Alone

As is evident from the first page of the Summary of the Proposed Restriction, this Proposal is based on a "concern" that all PFAS are very persistent, as opposed to demonstrating that they present an unacceptable risk to human health or the environment, as required by Article 68.1 of REACH. In fact, there is no reference to Article 68.1 at all in the Proposed Restriction, nor any demonstration that the conditions specified therein are met. The Proposed Restriction rather is based on a mere "concern". It reads as follows:

> *The main concern for all PFASs and/or their degradation products that are in the scope of this restriction proposal is the very high persistence, exceeding the criterion for very persistent (vP) according to Annex XIII of the REACH Regulation by far. Further supporting concerns are their bioaccumulation, mobility, long range transport potential (LRTP), accumulation in plants, global warming potential and (eco)toxicological effects.*

The Proposed Restriction appears to reflect a view by the Dossier Submitters that PFAS are non-threshold substances that should be treated as PBT/vPvB (as in the T-226/18 Court Case) and therefore any release into the environment suffices to demonstrate that they represent an unacceptable risk. As discussed above, PFAS as a group cannot be compared to the PBT/vPvB substances at issue in that case (nor is the situation similar to the T-226/18 Court Case). Also, the Proposed Restriction incorrectly assumes all PFAS are non-threshold substances (see further comments on page 15) as well as incorrectly assumes growing emissions and stock of PFAS in the environment (see further comments on pages 15-18).

Additionally, the Proposed Restriction confuses "unacceptable risk" with a "risk that cannot be adequately controlled." In particular, the Proposed Restriction starts from the premise that "any release should be considered a proxy for risk" to then concludes in the next sentence that due to the ongoing releases, "the risks are currently not adequately controlled" and this is an "unacceptable risk for human health and/or the environment."

The concepts of "unacceptable risk" and "risk not adequately controlled" are two distinct concepts. As the General Court held in Case T-226/18 (and confirmed by AG in her Opinion), a risk that is not adequately controlled may justify the preparation of an Annex XV Proposal in

[33] Opinion of Advocate General Kokott in Case C-558/21, para. 82.
[34] Ibid.

accordance with Article 69 REACH, but the actual adoption of a restriction by the Commission depends on whether there is an "unacceptable risk" in accordance with Article 68(1) REACH. It cannot be assumed that any risk that is not adequately controlled is necessarily an unacceptable risk. Whether a risk is "unacceptable" depends on many factors, including a comprehensive risk assessment, the appropriateness of the proposed restriction and its socio-economic impact.

Finally, as the Proposed Restriction is essentially based on a concern, lack of evidence and remaining 'uncertainties', the next question is whether the Proposed Restriction could be justified on the basis of the "precautionary principle", even though this is not claimed for in the Proposed Restriction itself and it would be legally questionable whether Article 68.1 REACH which requires a positive demonstration of an unacceptable risk allows restrictions to be based on uncertainties. The Proposed Restriction is not in compliance with the Precautionary Principle and could not be lawfully based on it for several reasons:

First, considering the ECJ ruling in case T-584/13 BASF Agro BV,[35] the criteria on applying the Precautionary Principle put forward by the Court has not been met by the Proposed Restriction as there is an absence of evidence on the effects of the vast majority of the substances being restricted, let alone evidence that any of the alleged effects would be 'adverse'.

Second, the Commission Communication on the Precautionary Principle provides that "the implementation of an approach based on the precautionary principle should start with a scientific evaluation, as complete as possible, and where possible, identifying at each stage the degree of scientific uncertainty."[36] The necessary elements of such "scientific evaluation" are specified in Section 5.1.2 of the Communication which refers to the four components of the risk assessment, namely hazard identification, hazard characterization, appraisal of exposure and risk characterization, which are also described further in Annex III of the Communication. The Communication then confirms that "[a]n attempt to complete these four steps should be performed before a decision to act is taken"[37]. It is clear these steps have not been followed in developing the Proposed Restriction. The alleged hazards and exposure of the PFAS substances have not been established, rather they have been postulated based on unsubstantiated assumptions. The Proposed Restriction does not address the fundamental requirements pursuant to the Precautionary Principle.

Third, according to the Commission Communication on the Precautionary Principle, a precautionary measure should be proportionate, non-discriminatory and consistent with similar measures, based on examination of the potential benefits and costs, subject to review and capable of assigning the responsibility for a more comprehensive risk assessment. It should not aim at achieving a zero risk and/or implement the most stringent/ onerous risk management option (such

[35] Judgement of the Court of 17 May 2018 in case T-584/13 BASF Agro BV, paragraphs 58-59, 65-68 (and case law cited).
[36] Communication from the Commission on the precautionary principle, COM/2000/0001 final, of 2.2.2000, p. 3.
[37] Ibid., p. 13.

as a total ban)[38]. The Proposed Restriction appears to be disproportionate and onerous in many respects.

Fourth, the Proposed Restriction should identify the measures that need to be taken in order to clarify the uncertainties that could justify precautionary measures. This is also a key requirement for the application of the Precautionary Principle. The Proposed Restriction does not identify the measures that should be taken to resolve the uncertainties. It simply proposes a total ban of all PFAS substances in all uses (except three time-unlimited exemptions), beyond some transitional periods.

Therefore, the Proposed Restriction is not in compliance with the Precautionary Principle and could not be lawfully based on it, since it does not respect the requirements set forth by the Court of Justice of the EU and the European Commission for the application of such principle.

III. THE PROPOSED RESTRICTION IS NOT PROPERLY GROUNDED IN A SOUND RISK ASSESSMENT

The Proposed Restriction does not follow ECHA's guidelines or recommended methods for hazard assessment[39] and risk characterization[40]. As discussed below, the Proposed Restriction provides only a general and qualitative narrative on a limited number of PFAS. As such, it does not fulfill the recommendations for scientifically assessing hazards and risks of PFAS exposure in humans or the environment. The Proposed Restriction acknowledges that there are data gaps for many PFAS compounds, indicating that the information presented is not representative of all PFAS in the proposed class. Thus, the conclusion of the Proposed Restriction that "the exposure of humans and the environment to these substances will inevitably lead to negative effects"[41] is not supported by the evidence provided, and as discussed below, is not based on an accurate, quantitative assessment of PFAS exposures and health effects.

A. The Proposed Restriction Does Not Follow ECHA Risk Assessment Guidance

As outlined in ECHA's "Guidance on information requirements and chemical safety assessment" ("IR&CSA") the goal of a human health or environmental risk assessment is to evaluate the potential for and likelihood of risk of adverse effects by comparing levels of exposure to levels expected to cause adverse effects[42]. Each component of a risk assessment requires quantitative assessment of chemical- and population-specific inputs, including toxicokinetics, mode of action, dose-response relationships, exposure pathways, exposure frequency, exposure duration, etc. Risk assessments comprise four general components: hazard identification, hazard

[38] Ibid.
[39] ECHA IR&CSA, Part B: Hazard assessment. Version 2.1, December 2011, available at: https://echa.europa.eu/en/web/guest/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment.
[40] ECHA IR&CSA, Part D: Framework for Exposure Assessment. Version 2.0, August 2016, available at: https://echa.europa.eu/documents/10162/17224/information_requirements_part_d_en.pdf/70da6d4b-5acf-40d9-8b75-1e1c311378df?t=1470841898389.; and Part E: Risk Characterisation.
[41] Proposed Restriction, p. 1.
[42] ECHA IR&CSA, Part E:Risk Characterisation, pp. 8, 21.

characterization (dose-response assessment), exposure assessment, and risk characterization. Each component is critical to making an informed assessment about the potential hazards of a specific chemical[43].

ECHA's IR&CSA recommends compiling all available data for a chemical and assessing that data for relevance, reliability, and adequacy as part of a hazard assessment[44]. The Proposed Restriction, however, fails to incorporate chemical-specific data required for risk or hazard assessment of individual substances. The absence of a proper and complete chemical-specific quantitative risk-assessment is evident throughout the text, which makes qualitative assumptions and statements, such as, "most of the PFASs can be expected to have several of the above listed properties of concern"[45]; "due to the immense number of PFASs and the lack of toxicological data for the vast majority of them, a combined assessment for all PFASs is unattainable"[46]; and "[c]larity on effects after repeated exposure of the diverse group of oligomeric/polymeric PFAS cannot be given on the basis of the available data"[47]. The Proposed Restriction does not attempt to address data gaps for persistence or other physical-chemical and/or toxicological properties for individual compounds using recommended read-across approaches intended for risk assessment purposes[48].

The Proposed Restriction would apply to numerous PFAS substances that have not been properly assessed for human health or environmental risks and solely relies on unjustified qualitative extrapolations from scarce and outdated data on mainly legacy PFAS, which have chemical and toxicological properties that differ substantially from those of many other PFAS. A rigorous and science-based risk assessment, per ECHA's own guidance, should instead be used to determine the most appropriate risk management action for specific PFAS compounds or established subclasses. Such an approach would require a clear understanding of which PFAS are found in the environment (water, soil, human biomonitoring), the origin of those PFAS found in the environment, a quantitative assessment of their properties, and quantitative comparison to levels of adverse effect.

B. Grouping All PFAS Is Not Suitable for Assessing Combined Effects or for Risk Assessment

In its discussion of potential combined effects of exposure to multiple PFAS compounds, the Proposed Restriction asserts that "a common mode of action is not a prerequisite for grouping chemicals for a combined exposure assessment and thus evidence for the same target organ is considered sufficient"[49]. The Proposed Restriction does not, however, establish that the target organ is the same for all PFAS. Further, the approach of combining multiple PFAS as a group for

[43] ECHA IR&CSA, Part B: Hazard assessment; Part D: Exposure assessment; Part E: Risk characterisation and Chapter R.11: PBT/vPvB assessment.
[44] ECHA IR&CSA, Part B: Hazard assessment, p. 7.
[45] Proposed Restriction, p. 33.
[46] Ibid., p. 32.
[47] Ibid., p. 31.
[48] ECHA Read-Across Assessment Framework (RAAF), p. 25.
[49] Proposed Restriction, Annex B, p. 189.

risk assessment purposes and/or applying equal potency for individual PFAS is not supported in the literature.

The Proposed Restriction also ignores multiple studies that discuss the limitations of combining PFAS for risk assessment according to their toxicities. Scialli et al. (2007) and Peters and Gonzalez (2011) independently evaluated the scientific feasibility of combining perfluoroalkyl exposures for risk assessment based on the critical concept of toxic equivalency factors, which was originally developed for dioxin-like compounds[5051]. Scialli et al. (2007) reviewed similar same-species studies performed with different perfluoroalkyls, and they found large discordance in endpoints measured for PFOS, PFOA, PFBS and PFDA[52]. These authors concluded that grouping those substances together for risk management purposes is not appropriate. Peters and Gonzalez (2011) also concluded that perfluoroalkyl exposure should not be combined due to the lack of support demonstrating consistent modes of action across species and PFAS compounds, which is fundamental for assessing potential exposure and effects of PFAS groups or mixtures[53].

Goodrum et al. (2021) suggested that, based on available data, concentration addition and relative potency factor methods are unsuitable for grouping mixtures of PFAS due to differences in modes of action and inconsistent dose-response patterns[54]. Colnot and Dekant (2022) reviewed the existing data and identified similar concerns[55].

Most recently, an expert panel emphasized that "the lack of consistent interpretations of human health risk for well-studied PFAS and the lack of information for the vast majority of PFAS present significant challenges for any mixtures risk assessment approach," and that "most experts agreed that 'all PFAS' should not be grouped together, persistence alone is not sufficient for grouping PFAS for the purposes of assessing human health risk, and that the definition of appropriate subgroups can only be defined on a case-by-case manner"[56].

Thus, the Proposed Restriction fails to consider the significant body of scientific literature and PFAS experts that have noted the lack of support for grouping all PFAS as a single class for regulatory purposes. Regulating PFAS as individual compounds is necessary for accurate assessment of potential hazards that consider substance-specific evidence regarding physical-chemical properties and toxicity information, as required by ECHA's own guidance[57]. The Proposed Restriction's failure to consider these publications adds to the deficiencies in its risk assessment approach. The Proposed Restriction also does not give any explanation as to why a significant body of scientific literature was not followed nor does it give any reasons as to why studies that consider risk-based information (dose-response assessments, mode of action) have not been evaluated.

[50] Scialli et al. 2007, as quoted in the References appendix to these comments.
[51] Peters and Gonzalez, 2011, as quoted in the References appendix to these comments.
[52] Scialli et al. 2007.
[53] Peters and Gonzalez, 2011.
[54] Goodrum et al. 2021, as quoted in the References appendix to these comments.
[55] Colnot and Dekant 2022, as quoted in the References appendix to these comments.
[56] Anderson et al. 2022, p. 1.
[57] ECHA IR&CSA, Chapter R.11: PBT/vPvB assessment (version 3.0, June 2017).

In addition, available toxicity data for PFAS compounds are heavily skewed towards certain PFAS chemicals which have different physical and chemical properties than and limited applicability to many other PFAS compounds. For example, many of the studies cited evaluated effects of PFOS and PFOA, which are generally no longer manufactured or used in Europe or the U.S, and, in any event, are not representative of all substances that fall within the OECD's broad definition of "PFAS."

IV. TOXICITY PROFILES OF PFAS DO NOT SUPPORT GROUPING

The Proposed Restriction provides only "a qualitative approach for the description of human health concerns with focus on endpoints considered most relevant for long-term exposure: repeated-dose toxicity (with targets most consistently affected by PFASs in experimental animals: liver, kidney, thyroid, immune system, and serum lipids), carcinogenicity, and toxicity to reproduction"[58]. This qualitative approach combined, with the significant data gaps for most PFAS, precludes classifying all PFAS as having similar toxicity profiles.

As demonstrated below, studies have not shown associations with the same health effects for all individual PFAS compounds or subgroups of PFAS, and not all endpoints have been tested across all PFAS; these facts prevent meaningful grouping of PFAS compounds based on toxicity. The Proposed Restriction states, "the strength of evidence is not the same for all effects and all PFASs, given that not all endpoints and all PFASs have been studied extensively"[59]. The Proposed Restriction also does not include doses at which effects in animals have been observed for any PFAS. Dose-response assessment is a fundamental component of the risk assessment process and is critical for comparing toxicities across any group of compounds[60].

Anderson et al. (2022) also acknowledge that there are significant uncertainties and variability in the toxicity or disease outcomes associated with PFAS exposure, as well as the mode of action across PFAS, which prevent broad grouping of PFAS compounds. The authors state, "even between the most well-studied PFAS, [PFOS] and PFOA, a consensus as to what adverse human health effects or disease may be associated with their exposure, has not yet been widely achieved"[61]. In addition, Anderson et al. note that slight differences in molecular structure can greatly impact predictions of toxicity. The expert panel concluded that it is "inappropriate to assume equal toxicity/potency across the diverse class of PFAS for human health risk assessment" (emphasis added)[62].

Thus, the Proposed Restriction does not justify that consistent human health effects would be expected across all PFAS in the proposed grouping.

[58] Proposed Restriction, Annex B, p. 148.
[59] Ibid., Annex B, p. 147.
[60] ECHA IR&CSA, Part B: Hazard assessment, p. 21.
[61] Anderson et al. 2022, p. 2.
[62] Ibid., p. 7.

A. The Proposed Restriction Incorrectly Assumes All PFAS are Non-Threshold Substances

The Proposed Restriction states that PFAS are "non-threshold" substances primarily due to their alleged persistence[63], but acknowledges that adverse effects from PFAS exposure occur after an "effect threshold" is exceeded[64]. Assumption of a non-threshold response implies that, for no PFAS is there a dose below which adverse effects are not expected to occur. According to ECHA's Guidance on Information Requirements and Chemical Safety Assessment[65], the distinction between threshold versus non-threshold substances is based on a mode-of-action assessment. Specifically, this guidance states, "for the human health end-points a distinction needs to be made between effects exerted by a threshold and non-threshold mode of action"[66]. For substances with a threshold effect, a quantitative risk assessment should be provided by deriving a "derived-no-effect level" (DNEL) and comparing it to levels of exposure[67]. This guidance also recommends that, even for substances that are considered to have a non-threshold mode of action (e.g., non-threshold mutagens and non-threshold carcinogens), a "derived minimal effect level" (DMEL) or a reference risk level considered to be of very low concern should be established[68].

Many of the purported health effects cited in the Proposed Restriction are considered threshold-based effects (e.g., liver, immune, thyroid, reproductive effects). The Proposed Restriction does not follow its own guidance (i.e., ECHA IR&CSA 2016, Part E) in that it fails to evaluate the mode of action for individual PFAS and does not establish either DNELs or DMELs for any PFAS[69]. Instead, the Proposed Restriction concludes that "it is considered impossible to establish a safe level for individual PFASs, let alone for the group in total"[70]. This conclusion contrasts with the approaches of other agencies that have calculated threshold effect levels for noncancer effects for individual PFAS compounds (e.g., EFSA's tolerable daily intake), as noted in the Proposed Restriction. ECHA therefore contradicts its own guidance as well as the evidence it presents in the Proposed Restriction by labeling all PFAS as "non-threshold" substances.

V. THE PROPOSED RESTRICTION IMPROPERLY RELIES ON FLAWED EMISSIONS DATA

The Proposed Restriction is based on the assumption that continued PFAS emissions could lead to increased "environmental stock," which is assumed to lead to increasing exposures exceeding known and unknown thresholds for adverse effects. Among other flaws (discussed above), the Proposed Restriction relies on outdated emissions data and default emissions parameters that show decreasing trends in PFAS emissions. These shortcomings are detailed below.

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[63] Proposed Restriction, Annex B.
[64] Ibid., Annex B, p. 4.
[65] ECHA IR&CSA 2016, Part E – Risk Characterisation.
[66] Ibid., p. 8.
[67] Ibid.
[68] Ibid., p. 8.
[69] Ibid.
[70] Proposed Restriction, Annex B, p. 191.

A. The Approach for Estimating Emissions is Flawed

The Proposed Restriction is based on a prediction that the stock of all PFAS in the environment will increase into the future. This rationale reflects an overly simplistic methodology that assumes product volumes are equivalent to the amount of PFAS used, which in turn is equal to the amount of PFAS emitted into the environment. The Proposed Restriction's methodology for calculating emissions and its underlying assumptions do not acknowledge that the number of goods sold cannot simply equal emissions to the environment; not only is the number of goods sold highly uncertain, but also the amount of PFAS used in products is usually extremely low. Furthermore, fate and transport considerations for PFAS that may enter the environment are critical for understanding environmental emissions.

In addition, current and future business priorities and trends estimate that most uses would be in industrial process with known and controlled manufacturing conditions (e.g., semiconductor manufacturing, pharmaceutical manufacturing) or in industrial uses with well-established end-of-life handling processes (e.g., automotive industry, medical-device industry), all of which limit environmental exposures[71].

The assumption that 'environmental stock' will continue to increase[72] would prove wrong for many PFAS that are neither mobile nor bioavailable. In the case of fluoropolymers, for example, no increasing environmental stock has been shown or would be expected[73]. Fluoropolymers also do not have long-range transport potential.

B. Current Data and Regulatory Trends Reflect Decreasing Manufacturing Emissions and Decreasing Environmental Concentrations in Europe

Some of the studies cited in the Proposed Restriction reflect historical emissions perspectives (e.g., Prevodouros et al. 2006) and do not represent more recent science, technological developments or industry initiatives for emissions control (e.g., EU POPs restrictions on the use, manufacture and placing into commerce of PFOA, PFOS and PFHxS, the U.S. Environmental Protection Agency's (EPA's) PFOA Stewardship Program, ChemService 2021). To control current and future emissions, PFAS manufacturers in Europe are already reducing emissions into the environment using state-of-the art technologies and closing production loops. The emissions of PFAS in the environment from the manufacturing activities are, in fact, decreasing.

For example, emissions data showing PFAS emissions from the 3M Zwijndrecht site in Belgium are below 0.1 mg/kg and continue to decrease (Figure 1).

[71] Wood, 2022, as quoted in the References appendix to these comments.
[72] Proposed Restriction, p. 3.
[73] Korzeniowski et al., 2022, as quoted in the References appendix to these comments.

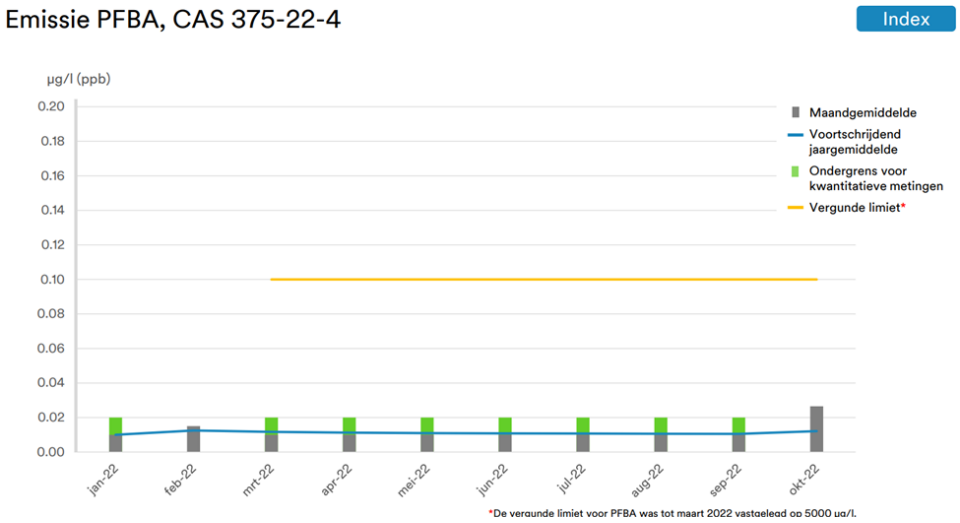

Figure 1. Example for PFBA water emissions from the 3M Zwijndrecht site

Note: Full information and water discharge emissions for other PFAS compounds can be found here: PowerPoint Presentation (3M.com). For air emissions please see information here: PowerPoint Presentation (3M.com).

In addition, permit conditions and limits under other existing and new EU legislation (e.g., revised EU Industrial Emissions Directive, revised EU EQS Directive; national permits in different EU Member States) have decreased in recent years and are predicted to further decrease in the future. These decreases will translate to emissions that are lower than those estimated in the Proposed Restriction. As an example, decreasing permit limits are shown in Table 1.

Table 1. Example of decreasing permit limits for PFAS discharges

Permits	**Old (2020)**	**New (2022)**
Belgium – 3M Zwijndrecht plant	PFBA: 5000 µg/l PFOS: 30 µg/l	0.1 µg/l (limit value in Flanders region since March 2022)

C. Inaccurate Estimation of PFAS Emissions Results in Flawed Conclusions Over the Proportionality of the Proposal

Although the Proposed Restriction notes that historical pollution is out of scope, the Dossier Submitters consider that a total ban of PFAS is proportional to risk regarding the cost of remediation associated with the past manufacturing of legacy PFAS substances (such as PFOS and PFOA). Not only is it contradictory that the risk assessment is based on these "out of scope" legacy PFAS emissions, but the Dossier Submitters also have not accounted for advances in PFAS treatment technology. Specifically, in recent years, multiple techniques have been developed and implemented to tackle the legacy and current PFAS emissions, as well as to treat PFAS-contaminated soil and water. Considering the number of uses that depend on critical performance of PFAS in many important applications, it is disproportionate to restrict all of them, particularly when there are more proportionate regulatory approaches available that could be implemented to

ensure that emissions, especially those occurring during manufacturing and end of life, are reduced and legacy emissions are cleaned up.

The conclusions of the Dossier Submitters regarding the proportionality of the Proposed Restriction cannot be supported. These conclusions are unjustified considering that the emission estimates listed are highly uncertain and based on historical data, while on the other hand the socio-economic impacts have probably been underestimated.

As demonstrated above, the Proposed Restriction relies on outdated data and default parameters (e.g., emission factors) that do not accurately reflect decreasing trends in emissions and improved control and remediation technologies. These decreasing trends also do not support the Proposed Restriction's core assumption that persistence will lead to increased environmental stock. Thus, proportionality of such a broad restriction proposal is not demonstrated.

VI. CONCLUSION

The Proposed Restriction does not justify the need for a restriction to manage the ten thousand strong group of substances defined as PFAS. REACH Restriction can only be justified if it is demonstrated that there is an "unacceptable risk." Risk requires both hazard and exposure assessment and cannot be equated to a concern alone. Furthermore, the Proposed Restriction contains several issues that do not represent an appropriate science-based and proportionate regulatory decision-making practice. The case for a blanket restriction of the entire PFAS group has not been justified.

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APPENDIX

THE EVALUATIONS OF ECOTOXICOLOGICAL EFFECTS DOES NOT COMPORT WITH BEST PRACTICES

Annex B of the Proposed Restriction presents the justification for PFAS grouping and evaluation of ecotoxicity of the group. As discussed here, Annex B does not meet the requirements for a proper ecotoxicological risk assessment and, as a result, fails to provide sufficient data or justification to support the application of limited effects data for a few PFAS compounds to thousands of individual PFAS compounds. In a review of PFAS ecotoxicity data by Ankley et al. (2021) and cited in the Proposed Restriction, 21 and 39 percent of the entire PFAS dataset were based solely on studies of PFOA and PFOS, respectively[74]. Additionally, 77 percent of the ecotoxicity studies are for PFSAs and PFCAs only. As discussed in Section III.B, PFAS have a wide range of physical-chemical properties (e.g., half-life, bioaccumulation,) which impact their potential toxicity. Extrapolating effects observed in the commonly studied PFOA and PFOS to other PFAS which have different environmental fate and effects is not appropriate and violates the principles of read-across assessment[75]. Further, the ecotoxicity data that are relied upon in Annex B have limitations based on the toxicity methodology and/or the interpretation of the toxicity response.

The following paragraphs highlight some of best practices that appear to have not been followed in assessing data quality, read-across and weight of evidence under risk assessment frameworks.

1. Toxicity Data for Ecological Receptors are Limited or Unavailable for Many Chemicals Within the PFAS Class

Of the more than 6,800 individual PFAS compounds in the ECHA database, Appendix B reports ecotoxicity data for fewer than 1 percent. Annex B acknowledges that "precise modelling of combined effects of all PFASs in the scope of the Proposed Restriction is realistically not achievable because of lack of data on toxicokinetics, toxicodynamics, slope of dose response curves as well as limited knowledge of the mode of action[76]. "For most PFASs, no data on effects are available"[77]. These gaps in ecotoxicity data for a large number of PFAS chemicals normally would preclude environmental risk management decisions due to the lack of ecotoxicity data (such as a predicted no-effect concentration) or would necessitate grouping based on quantitative structure–activity relationships (QSARs) to extrapolate toxicity data[78]. Though PFAS compounds previously have been evaluated and regulated for environmental toxicity by subgroup based on QSARs, PFAS have not been addressed as a comprehensive class. If the ECHA guidance were

[74] Ankley et al., 2021, as quoted in the References appendix to these comments.
[75] ECHA Read-Across Assessment Framework (RAAF).
[76] Borgert et al., 2004, as quoted in the References appendix to these comments.
[77] Proposed Restriction, Annex B, p. 189.
[78] ECHA IR&CSA, Chapter R.10: Characterisation of dose [concentration]-response for environment, May 2008, available at: https://echa.europa.eu/documents/10162/17224/information_requirements_r10_en.pdf/bb902be7-a503-4ab7-9036-d866b8ddce69?t=1322594768638/.

followed, PFAS compounds with ecotoxicity data would be evaluated individually, PFAS compounds without data would be grouped based on QSARs (if that information is available), and PFAS compounds without sufficient QSAR or mode of action data would be flagged for additional testing. Rather than following the established approach to environmental risk and toxicity evaluation[79], the Proposed Restriction makes broad assumptions based on limited data that may or may not be applicable to other chemicals. This goes against ECHA's own guidance and generally accepted best practices for performing risk assessments.

2. Ecotoxicity Data Summarized In Annex B Are Limited And Introduce High Levels Of Uncertainty

The data presented in Annex B are sourced from a review paper by Ankley et al. (2021). Relying upon the review rather than the underlying studies means that the study details were often overlooked and methodological flaws were minimized. This goes against ECHA's "Guidance on Information Requirements and Chemical Safety Assessment," which requires that studies should be evaluated for their reliability and conducted using standard methods (e.g., Good Laboratory Practices)[80]. In addition, extrapolations across species, durations, exposure scenarios and endpoints add to the uncertainty when toxicity effects are combined as a PFAS group. Ankley et al. (2021) commented, "The relative lack of toxicological data for PFAS as a broad class of compounds is a significant uncertainty facing ecological risk assessors. This shortcoming is manifested both in terms of the number/type of species for which there are toxicity data and the comparatively small number of PFAS that have been tested"[81]. Such limitations and uncertainties are discussed for each receptor group in the following subsections.

a. Aquatic Invertebrates

Information on aquatic invertebrate toxicity is largely based on the review from Ankley et al. (2021), rather than the primary literature. Several methodological issues mentioned by Ankley et al. (2021) likely influence the results. For example, Ankley et al. (2021) notes that the exposure scenarios (water only vs. water-sediment) may have resulted in different exposure concentrations but because toxicity estimates were based on nominal concentrations rather than measured concentrations, the effects values may not have reflected actual exposures[82].

Annex B relies on Ankley et al. (2021) and Mhadhbi et al. (2012) to compare sensitivity of marine and freshwater species to PFOA and PFOS. These two papers reported conflicting conclusions[8384]. Such uncertainties underscore the need to fill toxicity data gaps, rather than extrapolate insufficient data to thousands of chemicals.

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[79] Ibid.
[80] ECHA IR&CSA, Part B: Hazard assessment.
[81] Ankley et al., 2021, p. 588.
[82] Ibid.
[83] Ankley et al.
[84] Mhadhbi et al., 2012, as quoted in the References appendix to these comments.

b. Terrestrial Invertebrates

Annex B noted that "firm conclusions regarding the differences of the ecotoxicological effects of different PFAS groups in terrestrial invertebrates are not possible. The same applies for interspecies differences"[85]. Annex B then cites the same data from Ankley et al. (2021) to claim that trends in developmental toxicity were demonstrated across different PFAS groups. As with the assessment of aquatic invertebrates, the only paper cited was the Ankley et al. (2021) review; none of the underlying studies (including their methods, data and uncertainties) appear to have been reviewed.

c. Fish

Fish toxicity data presented in Annex B also were based on the Ankley et al. (2021) review, rather than the underlying studies. The fish toxicity data were not representative of a diverse group of species—more than 95 percent of the data were based on freshwater species (and nearly 60 percent of the data were for the Cyprinidae, *Danio rerio*).

Ankley et al. (2021) note that, for both acute and chronic exposures, PFAAs with shorter chain lengths were generally less toxic for certain fish than those with longer chains[86]. The differential toxicity observed across species indicates that PFAS compounds should not be treated as a collective group and that doing so overestimates potential risk to fish. This goes against ECHA's Read-Across Assessment Framework which states that if substances are grouped in a category, the ecotoxicological properties should be the same or follow a similar pattern[87].

d. Amphibians

The amphibian toxicity data presented in Ankley et al. (2021) are limited to a very few PFAS compounds, are not based on species native to Europe, and introduce a high degree of uncertainty due to variable test methods. The toxicity studies presented in Ankley et al. (2021) are based on eight PFAS, and most studies evaluated PFOS and PFOA[88]. These limited toxicity studies may not be applicable to the thousands of PFAS compounds for which no studies have been conducted. In addition, the toxicity studies that have been conducted have used four commonly tested species, none of which are native to Europe. The toxicity data are also based on a variety of methods using different exposure scenarios and life stages, which introduces additional uncertainty when these values are compiled for comparisons.

[85] Proposed Restriction, Annex B, p. 194.
[86] Ankley et al., 2021.
[87] ECHA Read-Across Assessment Framework (RAAF), p. 7.
[88] Ankley et al., 2021.

e. Birds

Acute and chronic toxicity on birds were reported only for PFOS, PFBS, PFHxS, and PFOA. Further, there were conflicting results on reproductive effects. For tree swallows, two studies reported decreased hatching success and a third reported no adverse effects.

The selected bird effects data also do not adequately account for other studies that did not show effects following exposure to PFAS (i.e., negative findings). For example, Blévin et al. (2017) found no relationship between PFAS body burdens and incubation temperature in Arctic black-legged kittiwakes[89], and Miljeteig et al. (2012) did not find relationships between PFAS levels in ivory gull and three endpoints[90].

f. Reptiles

The reptile toxicity data were based on five studies reviewed by Ankley et al. (2021). These studies focused primarily on PFOS and PFHxS and are, therefore, of limited value when estimating impacts for the thousands of PFAS compounds.

g. Other Animal Species

Ankley et al. (2021) compiled data on different animal species and effects of nine PFCAs, three PFSAs, three FTOHs, and three "novel PFAS." As with other animals, most data were available for PFOS followed by PFOA. Interspecies differences were difficult to evaluate in this context due to limited data[91].

In conclusion, the Proposed Restriction does not follow best practices because it relies on a limited and incomplete data set for ecological receptors that have uncertain toxicity testing methodology and other data gaps. These shortcomings prevent meaningful extrapolation of toxicity responses across species and PFAS compounds. Rather than following the established approaches to environmental risk and toxicity evaluation[92], the Proposed Restriction makes broad assumptions that do not justify such a broad restriction based on evidence for effects of PFAS exposure in ecological receptors.[93]

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[89] Blévin et al., 2017, as quoted in the References appendix to these comments.
[90] Miljeteig et al., 2012, as quoted in the References appendix to these comments.
[91] Ankley et al., 2021.
[92] ECHA IR&CSA, Chapter R.10: Characterisation of dose [concentration]-response for environment.
[93] As discussed more fully in 3M's comments, the Proposed Restriction also does not follow best practices with respect to its assessment of the potential human health impacts of PFAS. The Proposed Restriction acknowledges the significant data gaps regarding human health effects for most PFAS, stating: "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. For the vast majority of PFASs (estimated >99%), no data on repeated-dose toxicity, carcinogenicity, or reproductive toxicity is available" (*see* Proposed Restriction, Annex B, p. 141). As discussed in 3M's comments, the Proposed Restriction's evaluation of human health impacts fails to fully evaluate the evidence base, address data gaps, or conduct chemical-specific risk assessments, as required by relevant guidance and best practice.