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PFAS REACH Annex XV Restriction Report

1ST Public Consultation (22 March – 25 September 2023)

Regulatory & Legal Consistency of the PFAS Proposal for the REACH Restriction

1. Executive summary

Honeywell International Inc. (hereinafter - **Honeywell**)[1] is a global manufacturer and importer of various fluorinated gases to the European Union (**EU**), including hydrofluorocarbons (**HFC**) and hydrofluoroolefins (**HFO**) refrigerants and their mixtures (**blends**), primarily used in refrigeration, heating, ventilation and air conditioning (**RHVAC**), mobile air conditioning (**MAC**), thermal management systems (**TMS**) in electric vehicles (**EV**), propellants in medical dose inhalers (**MDI**) and insulation foams blowing agent applications, as well as a particular fluoropolymer - polychlorotrifluoroethylene (**PCTFE**) - used in the primary packaging of medicinal products and medical devices.

On 13 January 2023, the competent authorities of five EU/EEA states (**Dossier Submitters**) submitted the *PFAS REACH Annex XV Restriction Report* (**Proposal)** to the European Chemical Agency (**ECHA**).[2] As a responsible producer and supplier to the EU, Honeywell submits the following information and comments to the ECHA 1st public consultation on the Proposal aiming to justify exclusions of certain HFC/HFO gases and PCTFE fluoropolymers from the scope of the Annex XV dossier in question.

The Proposal **does not identify** by any appropriate means (e.g., IUPAC names, CAS or EC number) any of the 10,000 substances within its scope, contrary to *section II.3 of Annex XV REACH* as well as established regulatory and legal practices, including the principles of good administration, certainty, legality and equal treatment.[3]

Moreover, the ban on all ***"theoretical"*** substances in order to avoid *"regrettable substitutions",* without any objective assessments of the actual threats/risks, is disproportionate, aleatory, discriminatory, unscientific, and legally unfounded.[4] It is contrary to the core principles of the *REACH Regulation*[5], the general principles of EU law (proportionality, objective examination, good administration, subsidiarity and non-discrimination) and the wider EU policies, including the Green Deal and REPowerEU.

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1 See the list of acronyms and abbreviations (aligned with the Proposal) in **Annex I** below.

2 On 22 March 2023, ECHA published the *PFAS REACH Annex XV Restriction Report* in the Registry of restriction intentions until outcome and started the 1st *Annex XV report consultation* with a final deadline for comments on 25 September 2023.

3 See e.g., *Detlef Nolle v. Council of the European Union*, Case T-167/94, paragraph 73.

4 See e.g. *BASF Agro BV and Others v European Commission*, Case T-584/13, paragraphs 65-72: *"However, a preventive measure cannot properly be based on a purely hypothetical approach to the risk, founded on mere conjecture which has not been scientifically verified", BASF Agro BV and Others v European Commission*, Case T-584/13, paragraph 65; *"Moreover, those institutions may not take a purely hypothetical approach to risk and may not base their decisions on a 'zero risk", BASF Agro BV and Others v European Commission*, Case T-584/13, paragraph 72.

5 Hereinafter - ***REACH* Regulation** or ***REACH*** - *Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC* (as amended).

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Furthermore, numerous PFAS substances falling within the scope of the Proposal (i.e., OECD PFAS definition) do not share similar *physicochemical, toxicological and ecotoxicological properties, hazards, and exposure* (and consequently, do not pose equivalent risks, if any) which can be predicted by virtue of a simple structural similarity (-CF2- or CF3- moiety).[6] According to the most recent **EEAP 2022 Assessment Report**[7] and the majority of international experts *"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"* and that "*it is inappropriate to assume equal toxicity/potency across the diverse class of PFAS*".[8]

Contrary to what the Dossier Submitters indicate, there is a range of PFAS substances, including **various fluorinated gases**, that are not (v-)persistent (**not P/vP**) and **do not degrade to vP** substances in amounts leading to their risk characterisation as non-threshold substances with properties similar to PBT/vPvB substances. For instance, HFC-125, HFC-143a, HFO-1234ze(E), HFO-1336mzz(E), HFO-1336mzz(Z), HCFO-1233zd(E), HFC-245fa and HFC-365mfc ultimately degrade in the atmosphere to carbon dioxide (**CO_2**), Hydrogen fluoride (HF) and small amounts of the only PFAS arrowhead substance - trifluoroacetic acid (**TFA**).[9] These amounts are considered as *"minor source of TFA"* [10] resulting in *de minimis* increase in TFA concentrations and *"are well below the threshold for concern with respect to human and environmental health"*.[11] Also, comprehensive scientific evidence, including from *REACH* registration dossiers, confirms that many PFAS (comprising, HFC/HFO and PCTFE) are low hazard substances, not classified for any endpoint assessed in the Proposal (section 1.1.4)[12] and are safe for intended uses. Moreover, many of them are already comprehensively/**adequately regulated** in the EU and beyond.

The above conclusions are equally true for TFA for which the *REACH* registration data and Chemical Safety Report (**CSR**) (including, DNEL/PNEC assessments,[13] several times reviewed by ECHA) unequivocally demonstrate that it is not a non-threshold substance with similar risks to PBT/vPvB substances[14]. In this respect, the EEAP 2022 Assessment Report also concludes that *"based on projected future use of these precursors of TFA [incl. HFC/HFO], no harm is anticipated"* and that TFA *"is unlikely to cause adverse effects out to 2100*."[15]

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6 PFAS definition "*does not conclude that all PFASs have the same properties, uses, exposure and risks*", OECD, *Reconciling Terminology of the Universe of Per- and Polyfluoroalkyl Substances: Recommendations and Practical Guidance*, Series on Risk Management No. 61, 9 July 2021, p. 25.

7 See at page 25, *Environmental Effects of Stratospheric Ozone Depletion, UV Radiation, and Interactions with Climate Change*, 2022 Assessment Report, Environmental Effects Assessment Panel (EEAP), available at - http://ozone.unep.org/science/eeap

8 *Grouping of PFAS for human health risk assessment: Findings from an independent panel of experts*, J.K. Anderson, et al., 2022

9 See on TFA yields rates (molar) in Chapter 6, section 3.8, Fig. 12 and pages 314-319 of the EEAP 2022 Assessment Report; and EFCTC position paper *Published evidence supports very low yield of TFA from most HFOs and HCFOs*.

10 E.g., Chapter 6, Fig. 11 of the EEAP 2022 Assessment Report.

11 See in Chapter 6, section 3.8 of the EEAP 2022 Assessment Report.

12 The hazard assessment in section 1.1.4 of the Proposal, except regarding persistence, is particularly absurd as far as high-purity medicinal grade PCTFE fluoropolymers are concerned (see section 3.6 below).

13 *Section 6.5 of Annex I REACH* provides for possibilities of a *"qualitative risk assessment"* only for substances *"for which it was not possible to determine"* DNEL or PNEC thresholds. See e.g., *Global Silicones Council and Others v Commission*, Case T-226/18, paragraphs 194-196.

14 See the most recent comprehensive *Mammalian toxicity of trifluoroacetate and assessment of human health risks due to environmental exposure*, Dekant, *et al*., 17 February 2023; and *Scientific Assessment of Ozone Depletion: 2022*, GAW Report No. 278, 509 pp.; World Meteorological Organization (WMO): Geneva, 2022.

15 See pages 25 and 259 of the EEAP 2022 Assessment Report.

Finally, the Proposal lacks any **robust study** for allegedly new hazards of TFA or any other substance contrary to *Part I of Annex XV REACH.* The Restriction options (RO) contradict (concentrations, exclusions, derogations) restrictions on certain PFAS (groups) already included in *Annex XVII REACH* or currently under consideration by ECHA or the European Commission (section 2.2.1.2 of the Proposal). Moreover, the Proposal appears to lack important information submitted by stakeholders during the two previous Calls for Evidence (**CfE**)[16], including: on existing and foreseen risk management measures (**RMM**) for specific uses, **available alternatives** and their **safety/risks/costs,** uses of **substances already on the market**, **spare parts** and **second-hand articles**, as well as on the demonstrated **very high costs** for society if the proposed PFAS restriction is imposed. In this respect, the Proposal particularly lacks a robust risk assessment of substitutes for HFC/HFO gases and PCTFE. Based on the available evidence and objective assessments both HFC/HFO gases and PCTFE must be excluded from the scope of the proposed REACH restriction.

2. Legal framework

According to *Articles 68 and 69, and Annexes I and XI, of the REACH Regulation* and ECHA *Guidance on Annex XV dossiers for restrictions:*[17]

- *REACH* restrictions are justified when there is an unacceptable risk to human health or the environment, which is not adequately controlled and needs to be addressed at EU level, taking into account the socio-economic impact, including the availability of alternatives.
- The *Annex XV dossier* must provide sufficient information to support the restriction of all substances covered by the proposal, considering on a case-by-case basis for which substances in the group, a restriction is justified.
- Substances whose physicochemical, toxicological and ecotoxicological properties are likely to be similar or follow a regular pattern as a result of structural similarity and may be predicted from data for reference substance(s) within the group may be considered as a group.

Restriction dossiers should also follow the applicable legal standards and comply with all requirements of *Annexes I and XV REACH Regulation.*[18]

The present submission shall demonstrate that the Proposal infringes the statutory requirements as well as several general principles of EU law and contradicts wider EU policies; particularly when specific substances and their uses are assessed on a case-by-case basis.

3. Regulatory and legal analysis

3.1. Very high persistence as the sole criteria for a *REACH* restriction in comparison with other applicable EU regulations

The very high persistence characteristics of materials enables the durability and high performance of critical applications for the modern society (e.g., medical devices, transportation, renewable energy, aerospace, electronics). Durability of materials/products is needed for them to reach their technical

[16] *Call for evidence supporting an analysis of restriction options for PFAS* – May-July 2020, and 2 Stakeholder Consultation on a Restriction for PFAS - August-October 2021.

[17] *Guidance for the preparation of an Annex XV dossier for restrictions,* ECHA Guidance for the implementation of *REACH*, June 2007.

[18] ECHA and the European Commissions must follow criteria of *Annexes I and XV REACH* to decide whether there is an unacceptable risk, *Global Silicones Council and Others v Commission*, case T-226/18, paragraphs 192 to 199.

specifications and directly contributes to product safety, energy efficiency and circular economy goals via waste prevention.

According to the *REACH Regulation* and practices, persistence of a chemical in the environment may indeed trigger a certain level of potential concern. However, persistence alone is not enough to determine present or future *"unacceptable risks to human health and the environment"*. Further risk assessment measures should be taken, including hazard and emissions/exposure analysis in order to characterize the risk and to adopt adequate Risk Management Measures (**RMM**) for specific substances and uses.[19] Current or potential, *"hypothetical"* exposure alone without sufficient information on the effects on human health or the environment due to the intrinsic hazardous properties of a substance, cannot constitute an *"unacceptable risk"* under *Article 68 REACH*.[20] The EU authorities must positively demonstrate this high level of risk to justify a *REACH* restriction.

In this respect, the European Court of Justice consistently found that to establish the equivalent level of concern to PBT/vPvB substances, persistent characteristics of the substance in question should be underpinned (on a case-by-case basis) by *"scientific evidence of probable serious effects to human health or the environment"* similar to those of *Article 57(a) to (e) REACH*.[21]

The above requirements to demonstrate PBT/vPvB equivalent levels of concern, are not met in the Proposal, when specific substances and their uses are analysed on a case-by-case basis. This is contrary to the conclusions of the Dossier Submitters as will be demonstrated below and in further submissions to this consultation.

The EEAP 2022 Assessment Report provides for similar conclusions in Chapter 6, section 3.6.3 – *"our opinion is that persistence should only be considered as a regulatory criterion for substances that are moderately or highly toxic and/or are bioaccumulative in organisms and/or undergo trophic magnification."*

Very high persistence as the sole criteria for a potential *REACH* restriction of a very different vast group of substances, without sound case-by-case scientific analysis of emissions volumes and a risk assessment, is contrary to the EU's science-based regulatory system, and core EU legal principles (proportionality, objective examination, good administration, and legal certainty).

"To address PFAS with a group approach, under relevant legislation on water, sustainable products, food, industrial emissions, and waste" - as suggested by the *Chemicals Strategy for Sustainability Towards a Toxic-Free Environment communication*[22] - would be a more appropriate way of regulating.

A correct prioritisation of certain substances (sub-groups, where justified) for further *REACH Authorisation* process, could also be an appropriate regulatory measure. Even a separate EU regulation on very persistent substances and their uses (including, PFAS and their *"essential uses"*) would also be more adequate than the proposed bans, which are disproportionate[23] by comparison with potential

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[19] See on three elements of risk - hazard, exposure, and risk based on the hazard manifesting themselves in the exposure in, e.g. Sasol Germany and Others v Commission, T -661/19, paragraphs 25, 27, 62, 92 and 101; and *Etimine SA v. Secretary of State for Work and Pensions*, C-15/10, paragraphs 7, 13, 14, 55, 74, 75 and 80; found Sasol Germany and Others v Commission, Case T -661/19. Paragraph 62.

[20] *Ibid*. footnote 4 and *European Commission v Éditions Odile Jacob SAS*, Case C-404/10 P, paragraph 53.

[21] See e.g., *Chemours Netherlands v ECHA* (Case T-636/19, paragraphs 8, 34, 125 and 134); *BASF Grenzach GmbH v European Chemicals Agency* (Case T-125/17, paragraphs 128, 212 and 438); *Fédération des entreprises du commerce et de la distribution (FCD) and Fédération des magasins de bricolage et de l'aménagement de la maison (FMB) v Ministre de l'écologie, du développement durable et de l'énergie* (Case C-106/14, paragraphs 12 and 35).

[22] See page 14, *Chemicals Strategy for Sustainability Towards a Toxic-Free Environment*, Brussels, 14.10.2020, COM (2020) 667 final.

[23] *Haswani* v *Council*, C-241/19 P, para. 99; *Islamic Republic of Iran Shipping Lines and Others* v *Council*, C-225/17 P, para. 102 and the case-law cited). *See* also *Rotenberg* v *Council*, T-720/14, para. 178.

risks from many critical PFAS substances. The counterfactual will be very high costs for the society, market uncertainties and numerous legal actions.

3.2. PFAS definition and the regulation of specific substances

According to the Dossier Submitters: *"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)",* with limited exclusions (**PFAS definition**), shall not be manufactured, used or placed on the market as substances on their own, in another substance, as a constituent, in a mixture or in an article (above certain concentrations). Although the above definition is closely aligned with the OECD's PFAS definition (2021), the Dossier Submitters do not identify particular substances within the scope of the Proposal, contrary to the requirements *of section II.3 of* Annex XV *REACH* and the fundamental EU legal principles of legal certainty, good administration and proportionality.[24]

By failing to properly identify substances (CAS, EINECS, IUPAC, etc.) within the scope of the Proposal (*ca.* 10 000), the Dossier Submitters deprived the interested parties of the right to have their affairs handled *"impartially, fairly and within reasonable time"*, in accordance with *Article 41(2)(a) of the EU Charter of Fundamental Rights*. This is so, in particular, because it is impossible for stakeholders to provide "*all information, which might have a bearing on the results"* of the identified 10 000 substances and their uses.[25] Similarly, it is not credible that authorities would examine all the information carefully and impartially to deliver an adequately reasoned decision within 6 months and 60 days, according to the *REACH* consultation procedure on restrictions.[26] This concern is all the more valid, especially considering that the authorities in charge have a wide power of discretion in such technical issues.[27]

According to the Proposal, the *"main regulatory concern"* for the *REACH* restriction in question is that all PFASs and/or their degradation products falling under the scope of the PFAS definition, have very high persistency, exceeding the criterion of very persistent (**vP**) under *Annex XIII REACH*. Further *"supporting concerns"* are PFAS' bioaccumulation, mobility, long range transport potential (**LRTP**), accumulation in plants, global warming potential (**GWP**) and (eco)toxicological effects. PFASs enter the environment via emissions during the manufacturing phase, the use phase, and at the waste stage.

Further, in sections 1.1.2 on grouping, 1.1.6 on risk characterisation and in section 4, page 178, the Dossier Submitters conclude that all PFASs and/or their relevant degradation products, (as a group) exceed the vP criteria according to *Annex XIII REACH*, and *"[…] that PFASs should be treated as non-threshold substances for the purpose of risk assessment, similar to PBT/vPvB substances under the REACH regulation, with any release to the environment and environmental monitoring data regarded as a proxy for an unacceptable risk […] ".*

However, the 2021 OECD's PFAS definition is not conceived for regulatory purposes, which is also acknowledged by the Dossier Submitters. Moreover, according to the respective OECD report, it does not inform on the hazards of substances, even regarding their very persistent (vP) properties, or uses, exposure and risks.[28] In other words, the OECD itself is clear that its definition of PFAS was not intended

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[24] *Rotenberg* v *Council*, T-720/14, paras. 170-173. *Council* v *Manufacturing Support & Procurement Kala Naft*, C-348/12 P, para. 122.

[25] Potential *REACH* restriction should also ensure that the persons concerned to be able to precisely ascertain their rights and obligations and to take steps accordingly, *PlasticsEurope AISBL v. ECHA*, Case C-876/19 P, paragraph 136.

[26] Also see on the requirements of *"sufficient time"* in the *European Commission staff working document, Better Regulation Guidelines*, Brussels, 3 November 2021, SWD (2021) 305 final.

[27] See e.g., *Przedsiębiorstwo Energetyki Cieplnej sp. z o.o. v ECHA*, Case T-625/16, paragraph 89; *BASF and REACH & colours v ECHA*, case T-806/17, paragraph 75; *Technische Universität München v Hauptzollamt München-Mitte*, Case C-269/90, paragraph 14; and *Detlef Nölle v Council of the European Union and Commission of the European Communities*, Case T-167/94, paragraph 73.

[28] See pages 8 and 25, *Reconciling Terminology of the Universe of Per- and Polyfluoroalkyl Substances: Recommendations and Practical Guidance*, ENV/CBC/MONO(2021)25, OECD, 9 July 2021 (available here): *"The*

to be used for regulatory action because it is too broad to enable an effective, science-based risk assessment, which would result in regulation of these (over 10 000) chemical compounds as an entire group. The UK Health and Safety Executive (HSE) [29] service and US Environmental Protection Agency (EPA) [30] share the same opinion. Therefore, the PFAS definition in the Proposal should be further tailored to only address unacceptable risks to human health or environment, in accordance with *Articles 68 and 69 REACH*.

More precisely, the more adequate, objective, science-based and proportional approach is needed to address the main and supporting regulatory concerns of the Dossier Submitters directly in the PFAS definition. This could be done by limiting the scope of the PFAS *REACH* restriction to substances with specific properties of concern only, i.e., by their recognised persistent (P) and bioaccumulation (B) characteristics. In this respect the PFAS definition in the Proposal should consequently be amended as follows*:*

> *"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) and* ***meeting the REACH Annex XIII criteria on persistency and bioaccumulation****."*

It should be noted that RAC/SEAC supported a similar approach in the Restriction Proposal of microplastics (see the RAC opinion). In this process, the Dossier Submitters revised the *"microplastic"* definition several times before arriving at a suitable language (see section B.1.1.1, page 7, RAC Opinion). In this respect, RAC agreed that the starting definition of *"polymer"* in *Article 3(5) REACH* should be conditioned by specific intrinsic properties of *"microplastics"* - particles size, (bio)degradation and water solubility - that affect its hazard characteristics and result in vPvB equivalent concerns.[31]

The same approach is followed in the *REACH* restriction process for the PFAS use in fire-fighting foams, which is limited to a very targeted use of PFAS substances, in specific emissions/exposure conditions and based on corresponding risks assessments.

The EEAP 2022 Assessment Report experts panel shares similar views noting that, in addition to persistency characteristics regulatory criteria, should include moderate or high toxicity and/or bioaccumulation in organisms and/or trophic magnification properties (see Chapter 6, section 3.6.3 thereof).

By tailoring the PFAS definition for the *REACH* restriction, the Dossier Submitters will truly align the Proposal with OECD recommendations, which provide that: *"At the same time, individual users may define their own working scope of PFASs for specific activities according to their specific needs by*

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term "PFASs" 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."

[29] See also in section 1.3 of the Analysis of the most appropriate regulatory management options (RMOA), The UK HSE, April 2023, *"A generic PFAS definition may not be particularly useful from a regulatory perspective, and it may be more appropriate to consider regulatory approaches on the basis of particular PFAS groups and/or uses."*

[30] The US EPA also uses a narrower working definition of PFAS as "*Chemicals with at least two adjacent carbon atoms, where one carbon is fully fluorinated and the other is at least partially fluorinated"* in their National PFAS testing strategy (see in section 3) as well as their PFAS strategic roadmap. EPA's use of this working definition provides focus on PFAS of concern based on their persistence and potential for presence in the environment and for human exposure. Regarding degradation products, the EPA Office of Chemical Safety and Pollution Prevention have opined that *"trifluoracetic acid is a well-studied non-PFAS."*

[31] In this context RAC concluded in section B.1.2.2 of the Opinion on the *Restriction Proposal of microplastics* that *"although there are uncertainties in the understanding of the hazard and risk of microplastics, there is sufficient evidence to conclude that that they constitute an intrinsic hazard because of their long-term persistence in the environment in combination with their particulate form and potential to cause adverse effects"*.

combining the general definition of PFASs with additional considerations (e.g., specific properties, use areas).” [32]

The proposed amendments to the PFAS definition would also avoid a disproportionate spill-over of the *REACH* restriction to *“theoretical”* substances, which could be non-persistent and do not degrade to vP substances, as demonstrated is section 3.4 below.

3.3. Exclusion of specific non-P/vP substances

The disproportionately wide scope of the proposed PFAS definition is also evident when assessing specific substances, formally falling within the OECD definition and thus within the scope of the Proposal.

In this respect, Column 1 of the proposed restriction (page 4 of the Proposal) should include other non-persistent PFAS substances. There are certain fluorinated gases - HFC/HFOs refrigerants - that do not meet the vP criteria under Annex XIII *REACH* (e.g., atmospheric lifetime of HFOs is 10-70 days) and do not degrade in meaningful amounts/rates to other PFAS.

Indeed, there is robust scientific evidence that only a few mainstream fluorinated gases ultimately degrade to TFA in over 30% molar yields rates (e.g., HFO-1234yf, HFC-227ea, HFC-134a).[33] Many other HFC/HFO (HFC-125, HFC-143a, HFO-1234ze(E), HCFO-1233zd(E), HFC-245fa, HFC-365mfc, etc.) [34] have small estimated TFA atmospheric conversion yields and are *“minor source of TFA”* [35] resulting in *de minimis* increase in TFA concentrations. According to the conclusions of Chapter 6, section 3.8 of the EEAP 2022 Assessment Report, respective *“releases will add to the existing load of TFA in the environment but predicted amounts are well below the threshold for concern with respect to human and environmental health.”* In addition, according to valid *REACH* registration data (including CSRs), these non-vP substances do not pose levels of concern equivalent to PBT/vPvB substances, contrary to the conclusions in section 1.1.6 of the Proposal.

Moreover, considering current and projected (to 2100) TFA emissions resulting from atmospheric degradation of HFC/HFO substances and their effects on overall TFA concentration levels (see more details on TFA under section 3.6 below and the separate Honeywell submission on TFA), the risks to health and the environment from atmospheric emissions of these substances could not be considered unacceptable.[36][37] The proposed *REACH* restriction (ban) on all fluorinated gases is thus disproportionate to the alleged risks. The above fluorinated gases should be excluded from the scope of the restriction in question and their entire tonnages should not be considered for the emissions/exposure and baseline assessments in the Proposal.

3.4. Breach of *REACH* requirements for grouping

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[32] See page 25, *Reconciling Terminology of the Universe of Per- and Polyfluoroalkyl Substances: Recommendations and Practical Guidance*, ENV/CBC/MONO(2021)25, OECD, 9 July 2021 (available here).

[33] See detailed EFCTC position paper on the topic *Published evidence supports very low yield of TFA from most HFOs and HCFOs* ; see also detailed discussion in Chapter 6, section 3.2 of the EEAP 2022 Assessment Report.

[34] TFA yields rates (molar), see section 3.8, Fig. 12 and pages 314-319 of the *Environmental Effects of Stratospheric Ozone Depletion, UV Radiation, and Interactions with Climate Change*, EEAP 2022 Assessment Report.

[35] E.g., Chapter 6, Fig. 11 of the EEAP 2022 Assessment Report.

[36] See the most recent comprehensive *Mammalian toxicity of trifluoroacetate and assessment of human health risks due to environmental exposure*, Dekant *et al.,* 17 February 2023; *Scientific Assessment of Ozone Depletion: 2022*, GAW Report No. 278, 509 pp.; World Meteorological Organization (WMO), 2022; and Chapter 6, Section 3.8. in the EEAP 2022 Assessment Report.

[37] *“Current and projected (to 2100) concentrations of TFA in the oceans provide a very large margin of exposure (thousand-fold) when compared to thresholds of toxicity and risks to the environment and human health are **de minimis**.”*, Chapter 6, section 3.8. of the EEAP 2022 Assessment Report.

In accordance with *Section 1.5 Annex XI of REACH Regulation*:

> *"Substances whose physicochemical, toxicological and ecotoxicological properties are likely to be similar or follow a regular pattern as a result of structural similarity, may be considered as a group, or category, of substances. Application of the group concept requires that physicochemical 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 (read-across approach)."*

According to the *ECHA Read-Across Assessment Framework (RAAF)*:

> *"Applying the grouping concept (…) means that REACH information requirements for physicochemical, human health and/or environmental properties may be predicted from information from tests conducted on reference substance(s) within the group, referred to in this document as source substance(s), by interpolation to other substances in the group, referred to as target substance(s)." and " A separate assessment should be conducted for each information requirement intended to be fulfilled by the read-across approach".*

Moreover, according to ECHA's *Guidance on Annex XV for restrictions*:

> "*When preparing a restriction proposal, the Authority needs to consider on a case-by-case basis for which substances in the group a restriction is justified*". And further *"the Authority preparing a restriction proposal may wish to cover a number of related substances by the same Annex XV dossier. This could be the case 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 […]"*, and *"The Annex XV dossier has to provide sufficient information to support the restriction of all substances covered by the proposal."*

In view of the above, and contrary to the erroneous conclusions of the Dossier Submitters in section 1.1.2 of the Proposal, the grouping approach, as applied in the Proposal, is not justified for all PFAS substances within the scope of the Annex XV dossier. This is so, since not all PFAS have an equivalent hazard and risk that could be predicted from common structural -CF2- or CF3- elements, i.e., vP concerns or PBT/vPvB equivalent risks (persistency, bioaccumulation, mobility, toxicity, etc.). Exposure routs and volumes/tonnages of PFAS substances are also very different (i.e., fluoropolymers vs fluorinated gases) and cannot be predicted from the common structural elements, which is also in fact acknowledged by the Dossier Submitters (see section 1.1.5 of the Proposal).

In particular, it follows from *REACH* Registration dossiers and CSRs of many fluorinated gases (incl., HCFO-1233zd(E), HFO-1234ze(E), HFO-1234yf, etc.) that they do not meet the *REACH* Annex XIII criteria for being persistent (P) or very persistent (vP), or for persistent, bioaccumulative or toxic (PBT) substances, and do not pose vPvB equivalent risks. ECHA already scrutinised the respective scientific data and relevant assessments during various Dossier and Substance evaluations procedures. These substances could also not be considered non-threshold substances either, as they all have scientifically proven DNEL/PNEC levels for all relevant compartments, properly established in accordance with *Annex I REACH*.[38]

In other words, the aforementioned substances are not characterised by similar hazards, equivalent to vPvB substances due to their structural similarity of having -CF2- or CF3- moiety, as erroneously concluded in section 1.1.6 of the Proposal.

Similar conclusions are shared in the EEAP 2022 Assessment Report, which states that the majority of experts in the panel agree 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*

[38] Please see in more details in individual REACH registration dossiers.

appropriate subgroups can only be defined on a case-by-case manner" and that "*it is inappropriate to assume equal toxicity/potency across the diverse class of PFAS"*.[39]

The unscientific approach to grouping in the Proposal is even more apparent in the case of so-called *"theoretic"* PFAS substances covered by the Proposal. These innovative chemicals could be engineered in the future to avoid persistency and other properties of concern as well as for certain critical uses/applications with no emissions or alternatives. This commitment to constant innovation is legitimate and essential for a responsible chemical industry. For example, it was possible to achieve these properties in the case of the fluorinated gases HCFO-1233zd(E) (used as blowing agent in polyurethane foam insulation, solvent and refrigerant) and HFO-1234ze(E) (also used as a propellant for metered dose inhalers (MDIs)). These fluorinated gases were specifically engineered as a low-GWP and low toxic substances, without PBT/vPvB or equivalent risks properties and with TFA[40] degradation yields of low concern (2-30%).[41] This alteration leads to only negligible increases of TFA emissions and overall concentrations in the environment due to these gases. Contrary to the Dossier Submitters' summaries on page 5, section B.1.3, Annex B of the Proposal, these substances could not be considered as *"regrettable substitutions"* for the previous generation of HFC refrigerants to any reasonable extent. The same is true for many other so called *"last generation"* HFO refrigerants.[42]

The Proposal's approach to grouping is contrary to the very first recital (1) of the Preamble to the REACH Regulation, which provides that the Regulation "*should ensure"* among others *"free movement of substances […] while enhancing competitiveness and innovation"*. Moreover, restricting any substance without an appropriate risk assessment is contrary *to recital (23) of the REACH Regulation*, which mandates restrictions to *"be based on an assessment of those risks"*. Banning "theoretical" HFOs will also be contrary to several general principles of EU law, including proportionality (i.e., risk and objectives), objective examination (absence of any assessment), good administration[43] and legal certainty (double regulation)[44] as well as the free movement of goods/services/capitals, and the competitiveness and innovation policies enshrined in the TFEU (incl. Articles 28, 56, 63, 173, 179-190).

3.5. Use of misleading emissions data in the risk and baseline assessments

The annual emissions volumes of fluorinated gases in the environment in Table A.10 of Annex A and Table 1 of the Proposal, i.e., the key information for the Exposure assessment in section 1.1.5 of the Proposal, as well as in Table 11, section 2.4.3.2 for the Baseline environmental impact assessment, are misleading for the risk characterisation and environmental impact assessments purposes. This is because, as demonstrated in sections 3.1 and 3.2 above, many PFAS fluorinated gases are not classified as P/vP as such and do not fully degrade to TFA or other vP arrowhead PFAS on a one-to-one tonnages scale.[45] Therefore, total emitted tonnages of fluorinated gases as such, without considering the corresponding tonnages of final PFAS arrowheads (i.e. TFA), are not reliable and cannot be used to determine environmental and human exposure or for conducting impacts assessments. Hence, the overall conclusions from the emissions and exposure assessment (section

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39 See at page 278 of the EEAP 2022 Assessment Report; and in *Grouping of PFAS for human health risk assessment: Findings from an independent panel of experts*, J.K. Anderson, et al., 2022

40 Other ultimate degradation products are not PFAS.

41 See relevant discussion and conclusions in Chapter 6, sections 3.7.1-3 (SI 4.3.3-4) of the EEAP 2022 Assessment Report: "*It is clear from the above, that the small increases in tropospheric ozone formation generated from a transition from HFC emissions to emissions of HFOs would not be of concern."*

42 For detailed analysis and justifications for the exclusion of specific fluorinated gases please see further Honeywell submissions within this consultation.

43 The authorities in charge must *"to adopt its decision on the basis of all information which might have a bearing on the result derives in particular from the principles of sound administration, legality and equal treatment"*, *Oliveira SA v Commission of the European Communities*, Case T-73/95, paragraph 32.

44 The rules of law should be *"clear, precise and foreseeable in their effects", National Iranian Oil Company v Council of the European Union*, Case T-578/12, paragraph 112; *Deza v. ECHA*, Case T-115/15, paragraph 135.

45 Also acknowledged by the Dossier Submitters, see section B.4.1.3.2, Annex B of the Proposal.

1.1.5.) and the risk characterization (section 1.1.6.) in the Proposal (in particular that any PFAS emissions should be used as a proxy for risk) reflect a flawed and missing causality, and non-existent scientific and legal grounds.

3.6. Erroneous risk characterisation in the Proposal

In sections 1.1.2 on grouping, 1.1.6 on risk characterisation and 4 of the Proposal, the Dossier Submitters erroneously concluded that all PFASs and/or their degradation products within the scope (as a group) are very highly persistent, exceeding vP criteria according to *Annex XIII REACH*, and *"[…] that PFASs should be treated as non-threshold substances for the purpose of risk assessment, similar to PBT/vPvB substances under the REACH regulation, with any release to the environment and environmental monitoring data regarded as a proxy for an unacceptable risk […] ".*

To reach the above conclusions, the Dossier Submitters wrongly resort to the *"case-by-case risk assessment"* methodology in accordance with *para 0.10 of Annex I to REACH*. However, its application to substances properly registered under REACH (as reviewed by ECHA) and for which adequate human and environmental effects assessments and CSR under *Annex I* are available, is not justified.

For instance, many non-vP PFAS substances that degrade to TFA (including, fluorinated gases HFO-1234yf, HFO-1234ze(E), etc.) do not exhibit similar hazards as analysed in sections 1.1.4.2-1.1.4.9 of the Proposal, and erroneously attributed to all PFAS (i.e., *"supporting concerns"* - bioaccumulation, mobility, long range transport potential (LRTP), accumulation in plants, global warming potential and (eco)toxicological effects). Further on, the Dossier Submitters concluded that all PFAS should be treated as PBT/vPvB substances. However, the relevant REACH registration dossiers and CSRs univocally demonstrate that these substances do not pose health or environmental equivalent/similar risks to PBT/vPvB substances. All these substances also have scientifically established DNEL/PNEC and MoEs limits and even being potentially mobile and/or LRTP individually they are not characterised as non-threshold, like PBT/vPvB substances. Moreover, their CSRs demonstrate "negligible risks" for relevant exposure scenarios with defined/implemented RRMs, thus concluding that risks from these substances are "adequately controlled".

The same is true for the main PFAS degradation product of fluorinated gases - Trifluoroacetic acid (TFA). It is clearly confirmed in the *TFA REACH* registration dossier and its CSR that TFA could not be considered as a non-threshold substance with equivalent PBT/vPvB risks.[46] Moreover, there is solid scientific data already worldwide available (e.g., studies by the UNEP, OECD, EPA, *REACH* Registrations/Evaluation, individual scholars[47]) proving that TFA resulted from emissions of HFC/HFO (and HFO-1234yf, in particular) does not pose risks now nor in the foreseeable future.[48] All independent analysis demonstrates the minimal effects of HFC/HFO emissions on humans and the environment.[49]

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[46] E.g., "*The current low concentration of trifluoroacetic acid (TFA) produced by the degradation of several hydrofluorocarbons (HFCs) and hydrofluoroolefins (HFOs), is currently judged not to pose a risk to human health or to the environment.",* other EEAP reports, other SAP reports, see also EFCTC summary publications.

[47] See the most recent *Mammalian toxicity of trifluoroacetate and assessment of human health risks due to environmental exposure*, Dekant *et al*., 17 February 2023.

[48] "*TFA abundance and its environmental impacts have been assessed in many previous Assessments (e.g., Montzka, Reimann et al., 2011; Montzka, Velders et al., 2018; Carpenter, Daniel et al., 2018). Previous Assessments concluded that the environmental effects of TFA due to the breakdown of HCFCs and HFCs are too small to be a risk to the environment over the next few decades based on the projected future use of hydrocarbons, HCFCs, and HFOs.",* page 137, Scientific Assessment of Ozone Depletion: 2022, GAW Report No. 278, 509 pp.; WMO: Geneva, 2022

[49] E.g., "*UV-driven photodegradation of some of the compounds controlled by the Montreal Protocol (e.g., hydrofluorocarbons (HFCs)) produce contaminants such as trifluoroacetic acid (TFA), but concentrations of these breakdown products in the environment are currently deemed too low to be a concern for human health or the Environment"*, and *"TFA likely has natural geochemical sources, is widely used in industry and research laboratories, and is a by-product of the synthesis and degradation of fluorinated and perfluorinated compounds*

For instance, the most recent and comprehensive EEAP 2022 Assessment Report also unequivocally concludes that *"based on projected future use of these precursors of TFA [incl. HFC/HFO], no harm is anticipated"* and that TFA *"is unlikely to cause adverse effects out to 2100* as well as that "*TFA is of low toxicity in mammals",* and *"the risk to humans from residues of TFA in beer and tea are* ***de minimis*** *(of little importance)"* and its *"expected concentrations in the oceans and endorheic basins is several orders of magnitude and is indicative of* ***de minimis*** *risk".* [50]

In other words, many HFC/HFO refrigerants are well-studied substances, proved to be non-persistent (gases) and not exhibiting PBT/vPvB equivalent concerns according to *REACH*. These fluorinated gases do not degrade to TFA in quantities that would amount to unacceptable or uncontrolled risks. In this situation, the proposed indiscriminate application of the *"precautionary principle",* aiming to ban their use, is not justified. As already noted, there already is comprehensive scientific data and information on their applications, including in *REACH* registrations (and CSRs), the public domain and through two previous CfE.

Furthermore, the high molecular weight fluoropolymer - polychlorotrifluoroethylene (PCTFE), was specifically and intentionally engineered to be very persistent (vP) *"by design"* but at the same time to be safe for humans and the environment. Thus, it does not pose the hazards referred in section 1.1.4 of the Proposal. It is proven to be non-mobile, non-LRTP, non-bioaccumulation, non-accumulated in plants, non-(eco)toxic, ultra-low leaching, an inert material falling within the internationally recognised criteria of Polymers of Low Concern (PLC).[51] It is derived from the non-PFAS monomer CTFE (outside the scope of the Proposal) and there are no other PFAS involved in the PCTFE production process. According to available studies, it is also safe at the end-of-life stage, when landfilled (no leaching) and by municipal incineration under appropriate conditions take place.[52] In this respect, PCTFE incineration at end-of-life above 800 °C does not release PFAS-related materials nor trifluoroacetic acid (TFA). Therefore, the aforementioned assessments and conclusions of the Dossier Submitters regarding PBT/vPvB risks resulting from "supporting concerns" are erroneous and not scientifically justified.

It is also noteworthy that none of the robust study summaries, confirming the new information on allegedly hazardous "additional properties" of any PFAS substance, have been included in the Proposal, contrary to the last *paragraph of Part I, Annex XV REACH.*

In view of the above, in the Proposal, the Dossier Submitters failed to objectively and impartially assess and characterise risks based on *"as thorough a scientific evaluation of the risks as possible"*[53] for many PFAS (including, HFC/HFO, TFA and PCTFE). The final conclusions of the Proposal are therefore biased, erroneous and based on unjustified methodologies and scientific data.

3.7. Risks are adequately controlled

(PFCs)" … *"[b]ut available evidence indicates that this breakdown product is of minimal risk to human health"*, pages 8-9, Summary Update 2021 for Policymakers, UNEP Environmental Effects Assessment Panel.

[50] See pages 25 and 259 as well as Chapter 6m sections 3.6.1-2 of the EEAP 2022 Assessment Report.

[51] *Data analysis of the identification of correlations between polymer characteristics and potential for health or ecotoxicological concern*, OECD Environment, Health and Safety Publications, ENV/JM/MONO(2009*); A critical review of the application of polymer of low concern and regulatory criteria to fluoropolymers*, Henry, B. J., et al. (2018).; *A critical review of the application of polymer of low concern regulatory criteria to fluoropolymers II: Fluoroplastics and fluoroelastomers,* Korzeniowski, S. H., et al. (2022).

[52] See e.g. *Waste incineration of Polytetrafluoroethylene (PTFE) to evaluate potential formation of per- and Poly-Fluorinated Alkyl Substances (PFAS) in flue gas*, K. Aleksandrov, 2019; *Investigation of waste incineration of fluorotelomer-based polymers as a potential source of PFOA in the environment*, P.H. Taylor, 2009; Per- and polyfluorinated substances in waste incinerator flue gases, Bakker, J., et al. (2021), RIVM report 2021-0143; *Using mass defect plots as a discovery tool to identify novel fluoropolymer thermal decomposition products*, Myers, A. L., et al. (2014).

[53] *Pfizer Animal Health SA v Council of the European Union*, Case T-13/99, paragraph 162*; International Cadmium Association (ICdA) and Others v European Commission*, Case T-456/11, paragraph 52.

Full-life cycle emissions of many PFAS uses (e.g., fluorinated gases as refrigerants in RHVAC/MAC or PCTFE fluoropolymers in medicinal packaging) are already effectively and adequately controlled by other RMMs under relevant EU legislation. The *EU F-Gas Regulation*[54], *MAC Directive*[55] (F-Gas/MAC), ELV Directive[56], EMA requirements[57], medicines and veterinary laws[58], Medical Devices Regulation (MDR), EU waste and packaging laws[59] and other regulations mandate *inter alia* effective limitations on placing on the market (e.g., HFC (F-Gas) quotas and equipment bans), containment measures (HFC/HFO in RHVAC/MAC), product design and safety standards, disposal and end-of-life requirements (e.g., for medicinal packaging or vehicles). These regulations could be strengthened at any time, if warranted.

In this respect, HFC/HFO fluorinated gases (F-Gases) as refrigerants are only contained/function in RHVAC/MAC closed loop systems. Their emissions are subject to rigorous obligatory containment RRMs (on leaks controls, end-of-life collection, and disposal, etc.), under the EU F-Gas/MAC legislation. According to the very first words of *Article 1 of the F-Gas Regulation*, its key objective is the same as that aimed by the Proposal - reduction of emissions, i.e.: *"The objective of this Regulation is to protect the environment by reducing emissions of fluorinated greenhouse gases"*. According to the European Commission, F-Gas/MAC legislation is an example of a very successful regulation. Therefore, key uses of HFC/HFO substances are already adequately controlled from the perspective of the main objective of the *REACH* restriction Proposal. Grouping these substances with other potentially hazardous and less controlled PFAS within one *REACH* restriction process is disproportionate, flawed and legally unjustified.

In addition, TFA related risks due to emissions of fluorinated HFC/HFO gases, are adequately controlled also within the meaning of *section 6.4 of Annex I of the REACH* (as demonstrated in CSR). The current and projected concentrations of TFA are many fold lower than the established DNEL/PNEC and MoEs thresholds for relevant compartments, the adopted daily intake LW_{TW} values or drinking water standards.[60] Thus, human exposure to TFA from HFC/HFOs atmospheric degradation is also low (negligible), while upstream environmental emissions of these F-Gases are already subject to effective EU emissions/risks control measures (see above). Therefore, the conclusions in section 1.1.6 of the Proposal that all PFAS exhibit risks very similar to PBT/vPvB and that any PFAS emissions should be considered as a proxy for unacceptable risks, are erroneous, as far as HFC/HFO refrigerants are concerned.

The same is equally true for PCTFE fluoropolymers used in medicinal and medical device packaging, which satisfy the PLC criteria. Indeed, they do not involve other PFAS in their production, are placed

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54 *Regulation (EU) No 517/2014 of the European Parliament and of the Council of 16 April 2014 on fluorinated greenhouse gases and repealing Regulation (EC) No 842/2006* (as amended and currently under review, available here).

55 *Directive 2006/40/EC of the European Parliament and of the Council of 17 May 2006 relating to emissions from air conditioning systems in motor vehicles and amending Council Directive 70/156/EEC* (as amended).

56 *Directive 2000/53/EC of the European Parliament and of the Council of 18 September 2000 on end-of life vehicles (as amended)*

57 Aclar materials also comply with the current World Health Organisation ('WHO') and EU Guideline on Plastic Immediate Packaging Materials (see Guidelines on packaging for pharmaceutical products, WHO Technical Report Series, No. 902, 2002), relevant European Pharmacopoeia Monographs as well as the Directive 2002/72/EC and Regulation (EU) 10/2011 on plastic foods contact materials.

58 PCTFE-based fluoropolymers are only used as components of the *"immediate packaging", "closed container"* or *"primary packaging"* of final medicine products within the meaning of the EU legislation on regulation of medicinal products for human or veterinary use (i.e., Regulation (EC) No 726/2004, Directive 2001/83/EC, Directive 2001/82/EC).

59 Directive 94/62/EC on packaging and packaging waste; Directive 2008/98/EC on waste (Waste Framework Directive).

60 See in detail *Mammalian toxicity of trifluoroacetate and assessment of human health risks due to environmental exposure*, Dekant *et al.*, 17 February 2023.

on the market in very small tonnages resulting in negligible emissions during the full life cycle, are comprehensively regulated under EMA rules and EU laws on medicines/medical devices and can be safely disposed of through landfill and incineration.[61]

It is further noteworthy that the Restriction options (RO) envisaged in the Proposal contradict restrictions on certain PFAS (groups) already in place under *Annex XVII REACH* or currently under considerations in the EU or internationally (see section 2.2.1.2 of the Proposal). In particular, certain existing restrictions provide for different concentration thresholds, exclusions and derogations, as proposed in the current PFAS Proposal, creating legal uncertainties and suggesting a lack of proportionality between the actual risks of specific substances and their complete ban envisaged in the current Proposal. This also highlights a potential double regulation of substances that were previously comprehensively assessed and already regulated by *REACH* restrictions.

3.8. Absence of information on alternatives and specific uses

The Proposal is missing an objective and credible assessment of *"information on the risks to human health and the environment related to the manufacture or use of the alternatives"*, contrary to the requirements of *Part II, Section 3 of Annex XV REACH regulation*. Although Annex E and Appendix E.2 contain a general analysis on the availability and feasibility of alternatives (and their CLP classification), this analysis is selective, biased and ignores various pieces of evidence submitted during the two CfE preceding the Proposal.[62] In this respect, the Proposal lacks objective explanations on "*how their [stakeholders'] views have been taken into account",* contrary to the requirements of *Part II, Section 3 of Annex XV REACH regulation*.

The Dossier Submitters failed to perform a "*careful and impartial"* assessment of the submitted information,[63] omitting and using arbitrary (cherry picking) information in support to their positions only. For instance, please find Honeywell's submissions on *Fluorinated Products (FP)*, *MAC applications (incl. on TFA)* and *PCTFE fluoropolymers* (including the Information/Cover Notes) during the 2nd CfE consultation, resubmitted in Annex II below. It appears that none of this information on the conditions of use, was taken into account by the Dossier Submitters without any explanations, and contrary to the requirements of the last paragraph of *Part II, Section 3 of Annex XV REACH* and the principle of good administration.

It is noteworthy that regardless of the information provided by various stakeholders (over 600 submissions) during two CfE, the Proposal does not contain any analysis of the following important specific uses of PFAS substances: Thermal Management Systems (TMS) in Electric Vehicles (EV), chemical processing industry (equipment), pharmaceutical manufacturing, aerospace, military and defence, semiconductor manufacturing and many other critical PFAS applications. According to the Proposal, these uses will ultimately be banned upon the expiry of the 18 months transition period, without any assessment of the conditions of use or other justifications. This is unacceptable from the point of view of the effectiveness, proportionality, and good administration requirements applicable to *REACH* restrictions, contrary to *Annex XV REACH*, ECHA guidance documents and general principles of EU law.

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61 See detailed information on PCTFE in medicinal and medical devices packaging as well as on intrinsic properties of TFA, its concentrations in the environment and respective risks resulted from HFC/HFO emissions, in further Honeywell's submissions within this public consultation.

62 *Call for evidence supporting an analysis of restriction options for PFAS* – May-July 2020, and 2 Stakeholder Consultation on a Restriction for PFAS - August-October 2021.

63 I.e., under the EU general principle of good administration, *Detlef Nolle v. Council of the European Union*, Case T-167/94, paragraphs 7 and 73*; Przedsiębiorstwo Energetyki Cieplnej sp. z o.o. v ECHA*, Case T-625/16, paragraph 89; BASF and REACH & colours v ECHA, Case T-806/17, paragraph 75; *Technische Universität München v Hauptzollamt München-Mitte*, Case C-269/90, paragraph 14.

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Honeywell will provide additional information on specific uses of its products in subsequent submissions, as well as replies to specific information requests launched during this consultation.

4. Conclusions

Based on the evidence submitted above, Honeywell therefore concludes that the proposed PFAS definition, the identification of substances, the assessments of hazards, exposure, and risk, as well as the conditions of use in the Proposal, and the conclusions of the Dossier Submitters, are inconsistent with the *REACH* legal requirements. In particular, HFC/HFO gases as a sub-set of substances and PCTFE fluoropolymers must be excluded from the scope of the Proposal. Otherwise, the introduction of the *REACH* restriction based on the information and assessments provided in the Proposal, will be in breach of the *REACH* Regulation, EU general legal principles and wider policies. It will further result in very high costs to society.

Annex I - *List of acronyms and abbreviations*

Annex II – *Honeywell submissions within the 2nd Call for Evidence (CfE) on PFAS restriction*