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PFAS REACH Annex XV Restriction Report

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

Objective assessment of Trifluoroacetic acid (TFA) within the PFAS REACH Restriction Proposal

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**) 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**), as propellants in medical dose inhalers (**MDI**) and agents in insulation foam blowing applications.

On 13 January 2023, the competent authorities of five EU/EEA countries (**Dossier Submitters**) submitted the *PFAS REACH Annex XV Restriction Report* (**Proposal**) to the European Chemical Agency (**ECHA**).[2] Honeywell submits the following information and comments to the ECHA 1st public consultation on the Proposal.

Trifluoroacetic acid **(TFA)**[3] is formed in the atmospheric degradation processes for some HFCs and HFOs fluorinated gases.[4] For most HFC/HFO refrigerants, degradation rates/yields into TFA are small[5], resulting in *de minimis* increases in overall TFA concentrations by comparison with pre-existing TFA levels.[6] Only a few commercialized fluorinated gases decompose into fractions of TFA over 30% (including, HFO-1234yf, HFC-227ea, HFC-134a). Nevertheless, these emissions lead only to increases in TFA concentrations that safely remain at orders of magnitude below scientifically established DNEL/PNEC levels and/or food intake or water quality standards for TFA.[7]

According to the trifluoroacetic acid (TFA)[8] REACH registration dossier and Chemical Safety Report (**CSR**), this substance does not fulfil the criteria for a PBT or vPvB substance under Annex XIII REACH. Neither does it raise equivalent levels of concern under Article 57(f) REACH.[9] In this respect, ECHA

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

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 Honeywell also supplies the PFAS substance trifluoroacetic acid (TFA) to EU customers for laboratory analyses, scientific research and development purposes (SR&D). According to Article 67(1) REACH, this TFA use is excluded from REACH restrictions.

4 See also in section B.4.1.3.2, Annex B of the Proposal.

5 According to the conclusions in Chapter 6, section 3.8 of the *Environmental Effects of Stratospheric Ozone Depletion, UV Radiation, and Interactions with Climate Change*, 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."*

6 See e.g. detailed EFCTC position paper on the topic *Published evidence supports very low yield of TFA from most HFOs and HCFOs*.

7 See recent *Mammalian toxicity of trifluoroacetate and assessment of human health risks due to environmental exposure*, Dekant *et al.,* 17 February 2023; and all relevant previous UNEP (EEAP and SAP) reports.

8 Trifluoroacetic acid, EC no: 200-929-3, CAS no: 76-05-1, Molecular formula: C2HF3O2

9 See e.g., *Mammalian toxicity of trifluoroacetate and assessment of human health risks due to environmental exposure*, Dekant *et al*, 17 February 2023.

already reviewed/evaluated the TFA dossier without concluding that further regulatory actions were needed.[10]

Potential effects of HFC/HFO emissions on TFA concentrations and respective risks to humans and the environment were studied intensively worldwide. In this respect, highly qualified independent assessments of UNEP panels repeatedly concluded that *"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."* [11] and that *"available evidence indicates that this breakdown product [TFA] is of minimal risk to human health".*[12]

The most recent **EEAP 2022 Assessment Report**[13] unequivocally cited a common agreement among the majority of experts 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"* and that "*it is inappropriate to assume equal toxicity/potency across the diverse class of PFAS".*[14] According to the EEAP 2022 Assessment Report, this same argument applies to the inclusion of TFA, with a two-carbon chain and a single CF3 group, in a class with longer chain PFAS (e.g. PFOS).[15] The Report concludes that *"Trifluoroacetic acid has biological properties that differ significantly from the longer chain polyfluoroalkyl substances (PFAS) and inclusion of TFA in this larger group of chemicals for regulation would be inconsistent with the risk assessment of TFA"* (page 25).

This 2022 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"*.[16]

Moreover, according to the most recent 2022 UNEP/WMO report: *"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). Those 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."*[17]

Environmental fate and distribution modelling of TFA in the freshwater aquatic environment was conducted based on the assumption of constant and ongoing HFO emissions, which through atmospheric degradation in turn leads to a constant deposition of TFA. Initial modelling results demonstrate that within a short timeframe (months) a steady state concentration of TFA is reached, which does not further increase over time. This is illustrated in a case study for the Rhine basin (Germany, The Netherlands), for which TFA concentrations clearly below 10 µg/L are predicted.[18] Importantly, this study invalidates the incorrect assumption in the Proposal that TFA concentrations in fresh water would keep increasing until "inevitably" a toxic level would be reached.

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10 E.g., in 2017-2021, ECHA concluded comprehensive dossier evaluation of Trifluoroacetic acid, without indications of the need for further actions.

11 Page 9, *Environmental effects of stratospheric ozone depletion, UV radiation, and interactions with climate change:* UNEP Environmental Effects Assessment Panel, Update 2020

12 Pages 8-9, *Summary Update 2021 for Policymakers*, UNEP Environmental Effects Assessment Panel

13 *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

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

15 See pages 278 and 279 of the 2022 Assessment Report.

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

17 Page 137,*Scientific Assessment of Ozone Depletion: 2022*, GAW Report No. 278, 509 pp.; WMO, 2022.

18 Initial findings reported in **Annex II** below – Memorandum *"Trifluoroacetic Acid (TFA) Environmental Modelling"* - Ramboll Environment & Health, May 12, 2023. The full robust report will be soon submitted to ECHA within the course of this public consultation.

In addition, emissions of HFC are subject to effective Risk Management Measures (RMMs) under the *EU F-Gas Regulation,*[19] including progressively phasing down their tonnages via quotas (until 2030) and prohibitions on uses in certain RHVAC/MAC equipment. Emissions of HFOs (in particular, HFO-1234yf as the key MAC refrigerant) are also adequately controlled via containment requirements (leaks controls, end-of-life collection, and disposal, etc.) under the *MAC Directive*[20]and the *ELV Directive*[21]. The above EU legislation specifically aims to considerably decrease all HFC/HFO emissions in the short to medium term.

Considering the above, the conclusions in section 1.1.6 of the Proposal suggesting the existence of unacceptable risks from HFC/HFO emissions and their further degradation to TFA that are not adequately controlled and that all HFC/HFO emissions should be used as a proxy for unacceptable risks are erroneous, not proved by science and based on *"hypothetical"* or *"zero risk"* assumptions.[22] These conclusions are in contradiction with available solid scientific data, REACH registration information and ECHA practices.[23]

Therefore, in line with the provisions of Articles 68 and 69 REACH, fluorinated gases such as HFC-125, HFC-143a, HFO-1234ze(E), HCFO-1233zd(E), HFO-1336mzz(E), HFO-1336mzz(Z), HFC-245fa, HFC-365mfc, HFO-1234yf, HFC-134a, HFC-227ea, HFC-236fa, as well as TFA as a substance and as a degradation product of certain fluorinated gases must be excluded from the scope of the Proposal.

2. TFA formation processes and tonnages

There is strong evidence that TFA is a naturally occurring substance;[24] although the low hazard low-GWP fluorinated gas/refrigerant HFO-1234yf[25] and its predecessor HFC-134a[26] are considered to be potentially major anthropogenic sources for the atmospheric formation of TFA. HFO-1234yf was originally developed as a substitute for HFC-134a refrigerant for closed MAC and RHVAC systems providing the best available thermodynamic, electricity/fuel efficiency and safety features (incl. flammability, leaks, GWP and chemical hazard characteristics). HFO-1234yf is crucial for automotive MAC/RHVAC and transport refrigeration applications, which require non-persistent, not bio-accumulative substances, decomposing in the atmosphere in 5-15 days. The atmospheric degradation of HFO-1234yf leads to trifluoroacetyl fluoride ($CF_3C(O)F$, CAS 359-08-2)) which rapidly hydrolyses to yield trifluoroacetic acid (TFA).[27] The conversion rate of HFO-1234yf to TFA is almost 1:1 on a molar basis, with ~100% molar yield. The volumes of other degradation products, such as hydrogen fluoride (HF) and CO_2, are negligible.

Gaseous TFA is rapidly partitioned into water droplets in the atmosphere and deposited on land and surface waters via wet precipitation (rain, snow, and fog). Being a strong acid, upon contact with soil or surface waters, TFA quickly forms water-soluble salts with ions such as sodium, potassium, magnesium,

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19 *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).

20 *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).

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

22 "*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*", *"Moreover, those institutions may not take a purely hypothetical approach to risk and may not base their decisions on a 'zero risk'"*, see e.g. *BASF Agro BV and Others v European Commission*, Case T-584/13, para. 65 and 72.

23 Detailed analysis of the legality, regulatory and scientific consistency of the Proposal is provided in the previous *Honeywell submission reference no: bb6e00b6-571b-467a-ae79-7b046c6c9ab4*.

24 See also EFCTC summary publication *Naturally Occurring TFA*.

25 Polyhaloalkene, EC no: 468-710-7, CAS no.: 754-12-1, Mol. formula: C3H2F4

26 Norflurane, 1,1,1,2-tetrafluoroethane, EC no: 212-377-0, CAS no: 811-97-2, Mol. formula: C2H2F4

27 See e.g., *Trifluoroacetic acid deposition from emissions of HFO-1234yf in India, China, and the Middle East*, Liji M. David *et. all*, EGU, Atmospheric Chemistry and Physics Discussion.

and calcium, which are present in soils and surface waters. A large fraction of the formed TFA salts is transported by rivers and deposited into the oceans. It is very important to note that, in the environment, TFA salts behave in the same way as salts of other minerals. Where mineral-salts have accumulated in salt lakes, playas, and oceans, TFA-salts from natural and anthropogenic sources also accumulate.

In addition to HFO/HFCs, perfluorinated compounds such as pharmaceutical and plant protection (e.g., pesticides) products also contribute to TFA concentrations in the environment.[28] Although their potential contribution to the overall TFA concentration is estimated to be small. [29]

The statement of the Dossier Submitters that most PFAS substances containing a CF3- group (which includes HFC/HFO gases) *"are expected to ultimately degrade in the environment to TFA"* and thus *"will contribute to overall exposure and risks of PFASs"* (page 30 of the Proposal) is not scientifically accurate as far as objective risk characterisation is concerned. These predictions are incorrect and grouping the above fluorinated gases with other PFAS, for exposure/risk assessments, REACH restrictions and read-across purposes, is not justified.[30] [31]

Indeed, there is robust scientific evidence showing that few mainstream fluorinated gases ultimately degrade to TFA in molar yields rates over 30% (e.g., HFO-1234yf, HFC-227ea, HFC-134a).[32] Many other HFC/HFO (HFC-125, HFC-143a, HFO-1234ze(E), HCFO-1233zd(E), HFC-245fa, HFC-365mfc, etc.) [33] have small estimated TFA atmospheric conversion yields and are a *"minor source of TFA"* [34] resulting in *de minimis* increases 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."* Therefore, related risks are incomparable with effects from restrictions (bans) envisaged in the Proposal for all fluorinated gases. These HFC/HFO do not degrade to other PFAS either and thus should be excluded from the scope of the Proposal.

Moreover, considering the above, tonnages of TFA resulting from HFC/HFO degradation processes are considerably (probably, many folds) lower than estimated annual emissions tonnages of *"Applications of fluorinated gases"* provided in Table A.10 of Annex A and Table 1 of the Proposal and used for exposure/risk assessment purposes in the Proposal. Therefore, full annual emission volumes of these gases cannot be considered as a proxy for TFA emissions (i.e., the only PFAS finally cumulated in the environment) for the exposure and risk assessment purposes related to the Proposal. Thus, analyses and conclusions in section 1.1.5 and section 2.4.3.2 for the Baseline environmental impact assessments (see also Figure 7) in the Proposal are misleading, irrelevant and unreliable for the purposes of risk characterisation and environmental impact assessments.

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28 *Sources, fates, toxicity, and risks of trifluoroacetic acid and its salts: Relevance to substances regulated under the Montreal and Kyoto Protocols*, A report prepared by the UNEP Environmental Effects Assessment Panel and published in the Journal of Toxicology and Environmental Health B, 2016: DO, 2016: DOI1 February 2016, Report Number 2016-01.

29 *"There is a large uncertainty associated with the magnitude of other sources of TFA (e.g., potential natural sources, fluorinated pesticides, and pharmaceuticals)"*, see discussion on other TFA sources at pages 25, 283-289, *Environmental Effects of Stratospheric Ozone Depletion, UV Radiation, and Interactions with Climate Change*, EEAP 2022 Assessment Report.

30 See point 0.4 Annex I and section 1.5 Annex XI of REACH Regulation, also section 3.2 *ECHA Read-Across Assessment Framework (RAAF)*.

31 See pages 25 and 278 of the EEAP 2022 Assessment Report; and *Grouping of PFAS for human health risk assessment: Findings from an independent panel of experts*, J.K. Anderson, et al., 2022.

32 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.

33 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.

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

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3. Hazard and risk assessments

Contrary to the Dossier Submitter's conclusions in sections 1.1.4 and 1.1.6 of the Proposal, TFA does not exhibit hazards similar to PBT/vPvB substances. According to Chapter 6, section 3.8. of the EEAP 2022 Assessment Report, *"To regulate these substances ["all PFAS"] as a class (as has been suggested) is not scientifically defensible and TFA should be treated as a unique chemical for the purposes of regulation."*

In this regard, it was repeatedly concluded by various independent scientific bodies and scholars that TFA concentrations resulting from the degradation of fluorinated gases have limited (*de minimis*) effects on humans and the environment. [35]

3.1. Hazard assessment, non-threshold and PBT/vPvB classifications

TFA is classified under the EU CLP Regulation No 1272/2008[36] as a *Skin Corr. 1A* (like any strong acid), *Acute Tox. 4* and *Aquatic Chronic 3* substance[37]. Respective DNEL/PNEC levels were properly established for TFA in the REACH registration dossier and CSR. The fact that TFA is a persistent and mobile substance does not imply its classification as PBT/vPvB because TFA does not meet the criteria either for toxicity or for bioaccumulation. TFA is not considered to share equivalent concerns like PBT/vPvB substances, as demonstrated below and never challenged by ECHA.[38] Please also see detailed comments on toxicological and risk assessments for TFA made in the Proposal in the enclosed **Annex III**.[39]

- TFA is a strong acid and therefore (like any other strong acids) has certain hazards at high concentrations. However, these hazards are of no relevance for environmental concentrations. The toxic mode of action of TFA in acute studies (*Acute Tox, Cat 4 (inhalation)*) is due to its corrosive nature, being a strong acid.
- The toxicity observed in repeated dose studies was only for the liver, only at high doses, and only in the rats. This effect observed in the rat liver is irrelevant to human health considering its mode of action, which is well established to be rodent-specific.
- There is conclusive evidence that TFA is not to be classified for bioaccumulation endpoints. It is rapidly absorbed orally by animals and humans, included in the enterohepatic circulation, distributed in the body and excreted through urine and bile as the parent compound (i.e., TFA is not metabolized in the body and does not accumulate).
- There is conclusive evidence that TFA causes no thyroid toxicity, demonstrates no immunotoxic characteristics, teratogenic effects, or sensitisation effects.
- No developmental effects were seen in a PNDT study with rodents. However, foetal abnormalities in rabbits beyond the historical control incidence (primarily affecting the eyes) were observed at the two highest dose levels. This indicates a species sensitivity to this end point and needs further investigation. Although a NOAEL for embryo-foetal developmental toxicity was not established in the PNDT study in rabbits because of improper dose selection, the observed incident rates strongly suggest a threshold effect. There is enough toxicological data available to conduct a risk assessment for human health for TFA exposure using appropriate uncertainty factors.

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35 E.g. Chapter6, section 3.8, *EEAP 2022 Assessment Report*; *Environmental effects of stratospheric ozone depletion, UV radiation, and interactions with climate change: UNEP Environmental Effects Assessment Panel*, Update 2020, see also detailed EFCTC summaries.

36 Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006, (as amended).

37 TFA Summary of Classification and Labelling.

38 See results of TFA Dossier evaluation (2017-2021).

39 Detailed analysis of the legality, regulatory and scientific consistency of the overall Proposal is provided in the previous *Honeywell submission reference no: bb6e00b6-571b-467a-ae79-7b046c6c9ab4*.

- In conclusion, the Proposal has deemed the toxicity of TFA comparable with that of PFAS molecules with longer fluorinated alkyl chains (incl. PFOS). However, although TFA is persistent, its toxicity is not comparable to conventional longer chain PFAS molecules. TFA has a low Octanol/Water coefficient (Pow of 0.79) and does not trigger any bioaccumulation and biomagnification in the food chain and has not been classified as CMR after thorough scientific review of experimental studies. Thus, TFA cannot be categorized as having harmful properties similar to long chain PFAS molecules and/or exhibiting PBT/vPvB properties.

In addition, the recent 2023 *Mammalian toxicity of trifluoroacetate and assessment of human health risks due to environmental exposure* review summarised the available mammalian toxicity data of TFA and integrated this information with potential human exposure data based on the measured concentrations of TFA in water and food, using the margin of exposure methodology. According to the study, *"Based on recent levels of TFA in water and diet, MoEs for human exposures to TFA are well above 100 and do not indicate health risks."* [40] Regarding human risk characterisation, the study concludes that *"In summary, the approach using MoE does not indicate human health risks due to the presence of TFA in the environment and confirms previous assessments (EFSA 2014; Solomon et al. 2016)."* The above risk assessment peer reviewed publication concluded that the Margin of Exposure (MoE) of most humans is 4,000 to 476,000 times, indicating that the levels of TFA in the environment are several magnitudes below what would be considered toxic (see Table 2 thereof).[41]

The above conclusions, fully coincide with relevant assessments in Chapter 6, section 3.6.1 of the EEAP 2022 Assessment Report, 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)"*.

Regarding the environmental toxicology of TFA, the recent repeated study on freshwater green algae *Raphidocelis subcapitata* (formerly known as *Pseudokirchneriella subcapitata* and *Selenastrum capricornutum*) demonstrates that TFA is not toxic to aquatic organisms. Reliable toxicity data/studies are available for fish, invertebrates, aquatic plants, and algae (see above).[42] Hence, the current Aquatic Chronic 3 (long-term) classification must be re-assessed and may have to be removed.

Moreover, according to Chapter 6, section 3.6.2 of the EEAP 2022 Assessment Report, *"The margin of exposure between the distribution of NOECs and the observed and expected concentrations in the oceans and endorheic basins is several orders of magnitude and is indicative of **de minimis** risk."*

As correctly concluded in Chapter 6, section 3.6.3 of the EEAP 2022 Assessment Report, *"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. TFA does not bioaccumulate nor is it toxic at the low to moderate exposures currently measured in the environment or those predicted in the distant future."*

3.2. TFA concentrations from HFC/HFO emissions

In a series of reports from 2016 to 2022, the United Nations Environment Programme (UNEP) Environmental Effects Assessment Panel (EEAP) and Scientific Assessment Panel (SAP) repeatedly concluded that TFA has been found at levels that are far below those that would be considered toxic to humans or the aquatic environment, and will not reach these levels for decades. This is particularly true for TFA formed from the degradation of fluorinated gases.

For instance, the 2020 report by the UNEP EEAP concluded that *"The current low concentration of trifluoroacetic acid (TFA) produced by the degradation of several hydrofluorocarbons (HFCs) and*

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

[41] According to conclusions in Chapter 6, section 3.8 of the EEAP 2022 Assessment Report, *"Salts of TFA have low toxicity to animals and plants and there are very wide margins between current/projected exposures and toxicity values."*

[42] See on Aquatic toxicity in TFA REACH registration dossier.

hydrofluoroolefins (HFOs), is currently judged not to pose a risk to human health or to the environment."[43]

The most recent EEAP 2022 Assessment Report also concluded that *"These 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".*[44]

In addition, according to the most recent World Meteorological Organisation (WMO) report, "*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."*[45]*.*

It is also important to highlight that although the comprehensive UNEP and WMO studies referenced above acknowledge that humans could be exposed to TFA via drinking water and food, they explicitly state that there is no evidence to date of adverse effects on human health.

Environmental fate and distribution modelling of TFA in the freshwater aquatic environment was conducted based on the assumption of constant and ongoing HFO emissions, which through atmospheric degradation in turn leads to constant deposition of TFA. Initial modelling results demonstrate that a steady state concentration of TFA is reached within a short timeframe (months), and does not further increase over time. This is illustrated in a case study for the Rhine basin (Germany, The Netherlands), for which TFA concentrations clearly below 10 µg/L are predicted.[46] Importantly, this study invalidates the incorrect assumption in the Proposal that TFA concentrations in fresh water would keep increasing until "inevitably" a toxic level would be reached.

Under these circumstances, it is evident that the conclusions in section 1.1.6 of the Proposal that all PFAS are characterised by being equivalent to PBT/vPvB substances, and all PFAS emissions should equally be considered as a proxy to unacceptable risks, are erroneous if and when TFA concentrations from emissions of HFC/HFO are properly assessed. The respective conclusions of the Dossier Submitters are based on *"hypothetical"* and *"zero risks"* assumptions that even from the precautionary point of view are not justified.

3.3. Risks are adequately controlled

Emissions of HFC are subject to effective Risk Management Measures (RMMs) under the *EU F-Gas Regulation*. Use of those fluorinated gases will be progressively phased down until 2030 by virtue of rapidly decreasing quota volumes and prohibitions on uses in certain key RHVAC/MAC equipment.[47]

According to the very first words of *Article 1 of the F-Gas Regulation*, its key objective is the same as that of the Proposal - reduction of emissions, i.e.: *"The objective of this Regulation is to protect the environment by reducing emissions of fluorinated greenhouse gases"*.

In addition, emissions of HFOs (in particular, HFO-1234yf as the key MAC refrigerant) are subject to severe containment requirements (mandatory leaks controls, certification of services, end-of-life

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[43] Page 9 of the UNEP Environmental Effects Assessment Panel, *Summary Update 2020 for Policymakers* - https://ozone.unep.org/sites/default/files/assessment_panels/EEAP-summary-update-2020-for-policymakers.pdf

[44] Page 292 of the EEAP 2022 Assessment Report.

[45] Page 137, *Scientific Assessment of Ozone Depletion: 2022*, GAW Report No. 278, 509 pp.; WMO: Geneva, 2022

[46] Initial findings reported in **Annex II** below – Memorandum *"Trifluoroacetic Acid (TFA) Environmental Modelling"* - Ramboll Environment & Health, May 12, 2023. The full robust report will be soon submitted to ECHA within the course of this public consultation.

[47] *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); also see on its review process here.

collection, and disposal, etc.) under the EU *MAC Directive*[48]and the *ELV Directive*[49] that also aim to considerably decrease HFC/HFO emissions and exposure on a short-term basis.

In this respect, although the fluorinated gas HFO-1234yf[50] degrades in the atmosphere to TFA in high molecules yields (i.e., 1:1), HFO-1234yf is non-persistent (i.e., atmospheric lifetime 5-15 days), low-GWP, and a low hazard gas without equivalent PBT/vPvB concerns. Its containment and emissions in MAC and EV TSM systems (main uses) are subject to comprehensive RMMs under the *MAC Directive* and *ELV Directive.* As demonstrated above, HFO-1234yf degradation to TFA does not pose unacceptable risks either (1) because of low-hazard properties (not PBT/vPvB equivalent risks) and (2) low current and predicted concentrations (by multiple orders of magnitude) of TFA resulting from degradation processes.[51] In other words, HFO-1234yf should be excluded from the scope of the Proposal because it is not persistent and its only persistent degradation substance TFA poses no unacceptable risk, as well as being adequately controlled by other RMMs.

Therefore, as demonstrated above, key uses for HFC/HFO gases and the respective TFA emissions and exposure are already adequately controlled across the EU through existing regulatory measures. RMMs provided in the TFA CSR also ensure that all respective potential risks remain negligible. Under these circumstances, the proposed PFAS restriction on HFC/HFO gases is not scientifically justified and is excessive and disproportionate to emissions and corresponding TFA formation risks, as demonstrated in sections 3.1 and 3.2 above.

4. Conclusions

The most common HFC/HFO gases must be excluded from the scope of the PFAS restriction Proposal because they are low hazard, not persistent substances according to Annex XIII REACH. They degrade in the atmosphere to minimal TFA quantities that result in TFA concentrations at magnitudes far below any established DNEL/PNEC thresholds or acceptable intake levels (water/food). Extremely low current and predicted levels of TFA concentrations unequivocally confirm the absence of unacceptable risks within the meaning of Title VIII REACH. Moreover, objective assessments of all available scientific data on TFA justify the exclusion of this substance from the scope of the Proposal.

Furthermore, a 2023 modelling study on the redistribution of TFA concentrations across the Rhine basin (Germany, The Netherlands) also confirmed that TFA concentrations in fresh water rapidly reach a steady state and that its concentration is well below any sensitivity thresholds, and will not continue to increase “forever” contrary to the assumptions of the Proposal.[52]

Respective risks are already adequately controlled by EU-wide RMM? that may be adjusted at any time. In this respect, short atmospheric lifetimes of many HFO gases allow effective and rapid interventions, whenever warranted.

Introducing the REACH restriction under these circumstances will be disproportionate, will violate the REACH Regulation, EU general legal principles and wider policies, and will result in very high costs on society.

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48 *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).

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

50 Polyhaloalkene, EC no: 468-710-7, CAS no.: 754-12-1, Mol. formula: C3H2F4. Please consult the respective REACH registration dossier and CSR.

51 See e.g, *Trifluoroacetic acid deposition from emissions of HFO-1234yf in India, China, and the Middle East*, Liji M. David *et all*, EGU, Atmospheric Chemistry and Physics Discussion.

52 Initial findings reported in **Annex II** below – Memorandum *“Trifluoroacetic Acid (TFA) Environmental Modelling”* - Ramboll Environment & Health, May 12, 2023. The full robust report will be soon submitted to ECHA within the course of this public consultation.

Therefore, Honeywell submits that the fluorinated gases HFC-125, HFC-143a, HFO-1234ze(E), HCFO-1233zd(E), HFO-1336mzz(E), HFO-1336mzz(Z), HFC-245fa, HFC-365mfc, HFO-1234yf, HFC-134a, HFC-227ea, HFC-236fa, HFC-227ea and TFA as a substance and as a degradation product of certain fluorinated gases must be excluded from the scope of the Proposal.

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Annex I - *List of acronyms and abbreviations*

Annex II *– Memorandum of the Initial findings "Trifluoroacetic Acid (TFA) Environmental Modelling" - Ramboll Environment & Health, May 12, 2023. The full report will be soon submitted to ECHA within the course of this public consultation.*

Annex III *- Comments on TFA toxicologic and risk assessments in the Proposal for PFAS REACH Restriction*