Honeywell

HONEYWELL ADVANCED LIMITED
Riverview House
Harvey's quay Apartments
Limerick V94R3DE
Ireland

22 September 2023

PFAS REACH Annex XV Restriction Report

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

Exclusion or time-unlimited derogation of HFO-1234ze(E) propellants in technical aerosols applications from PFAS REACH restriction proposal.

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**). In particular, Honeywell supplies the gas **HFO-1234ze(E)**[2] for uses as **propellants in technical aerosols** applications, including as dust removal sprays in various important industries (semiconductors an automotive manufacturing, train maintenance, etc.), as disinfectant sprays (e.g., in aircrafts), lubricants, novelty sprays or those used to test smoke detectors, and others.

On 13 January 2023, the competent authorities of five EU/EEA Members States (**Dossier Submitters**) submitted to the European Chemical Agency (**ECHA**) the *PFAS REACH Annex XV Restriction Report* (**Proposal**).[3] Substance HFO-1234ze(E) falls within the definition of PFAS used in the Proposal.

Dossier submitters indicated in the restriction Proposal (Proposed restriction - Annex XVII entry PFASs) that the following potential derogation is marked for reconsideration after the Annex XV report public consultation: *"z. [propellants for technical aerosols for applications where non-flammability and high technical performance of spray quality are required until 13.5 years after EiF"* (i.e., entry into force (EiF) of the PFAS restriction).

In this respect, contrary to the information provided at page 245, Annex E.2.8 of the Proposal, suggesting that *"HFO-1234ze has been found to be a highly flammable gas in combustion experiments"*, Honeywell submits that this allegation is not correct as far as HFO-1234ze(E) uses as propellants in technical aerosols applications are concerned. (Please see respective assessment in section 2.1 and Annexes II-V below).

In addition, contrary to what the Dossier Submitters claim, there is a range of PFAS substances, including various fluorinated HFC/HFO gases that are low-hazard, have low-Global Warming Potential (GWP), not (v-)persistent (not P/vP) and do not degrade to vP substances in any meaningful amounts. For instance, the REACH registration dossier and Chemical Safety Report (CSR) for the fluorinated gas HFO-1234ze(E) contain conclusive scientific evidence demonstrating that this substance is not persistent and does not exhibit risks similar to PBT/vPvB substances under Article XIII REACH.

According to the most recent scientific data, upon release HFO-1234ze(E) ultimately degrades in the atmosphere to carbon dioxide (CO_2), Hydrogen fluoride (HF) and, in approx. 19 days, to an insignificant (ca. 2%) and thus negligible amount of the only PFAS arrowhead substance - trifluoroacetic acid (**TFA**).[4]

---

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

2 1-Propene, 1,3,3,3-tetrafluoro-, EC no: 471-480-0, CAS no.: 1645-83-6, Mol. formula: C3H2F4

3 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.

4 See Fig. 12 at page 282 and sections SI 4.3.2 at page 317 of the of the *Environmental Effects of Stratospheric Ozone Depletion, UV Radiation, and Interactions with Climate Change*, EEAP 2022 Assessment Report.

The respective TFA amounts results in *de minimis* increases in overall TFA environmental concentrations by comparison with pre-existing TFA levels. [5] [6]

In this respect, highly qualified independent assessments ongoing for several years already by UNEP panels repeatedly conclude 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."* [7] and that *"available evidence indicates that this breakdown product [TFA] is of minimal risk to human health".* [8] The most recent 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"*.[9]

In this regard, *Q&A 10 of Addendum to the EEAP Assessment Report* also confirmed that "*Now and in the distant future, predicted TFA concentrations in surface waters and terminal basins are thousands of times less than thresholds of concern for human or environmental health*." [10]

Detailed analysis on degradation of HFC/HFO and relevant hazard, exposure and risks assessments of TFA is provided in the Honeywell submission reference no: 76bb3d12-2101-4390-82cf-3498b47e8015.

Therefore, the Dossier Submitters erroneously considered (in section 1.1.6 of the Proposal) HFO-1234ze(E) together with other PFAS (i.e., as a group) for the hazard, exposure and risks characterisation purposes. They also erred when concluding that HFO-1234ze(E) is being among *"non-threshold substances"* with the overall concerns *"very similar to those of the PBT/vPvB substances"* and using its emissions *"as a proxy for risk"*.[11]

Moreover, HFO-1234ze(E) as a propellant in technical aerosols is subject to rigorous risk management measures (RMMs) provided under *EU F-Gas Regulation* , *Biocidal Products Regulation (BPR)*[12] (for e.g. disinfectants) and in relevant industry standards. For example, in the aerospace sector individual airlines may specify aerosol products containing HFOs in their current technical specifications. This could mean lengthy recertification process for these products in the event of a restriction.

Considering that all emissions of propellants occur at the use stage, all respective risks are already adequately controlled and the proposed REACH restriction (i.e., ban) is disproportionate and excessive within the meaning of Articles 68 and 69 REACH resulting in a *"double regulation"*.

As correctly highlighted in sections E.2.8 and E.2.8.2.5. of Annex E of the Proposal all potential alternatives to HFO-1234ze(E) are not suitable for applications in technical aerosols for various reasons. For instance, HFC-32 is flammable F-gas with high GWP of 771.[13] The same is true for other HFC gases, such as HFC-134a and HFC-152a. These are clearly *"regrettable substitutions"* in applications in question. Nitrous oxide is also a flammable oxidiser which could be used as a recreational drug with serious health effects. Other potential substitutes are all hydrocarbons with significant flammability risks that cannot be used in many industries (e.g., aerospace, enclosed spaces and application near a

---

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

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

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

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

10 Q&A 10*, Questions and Answers about the Effects of Ozone Depletion, UV Radiation, and Climate on Humans and the Environment*, EEAP 2022 Assessment Report.

11 See analysis and conclusions of section 1.1.6 (Risk characterisation) of the Proposal.

12 Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products.

13 See Table 7.SM.6 at pages 17-18 of *The Earth's Energy Budget, Climate Feedbacks and Climate Sensitivity Supplementary Material,* IPCC AR6 Report, 2021.

flammable source) and exhibit serious safety issues from a manufacturing perspective. Not-in-kind alternatives such as compressed gases have inferior spray quality and are not appropriate for many applications (e.g. lubricants for vehicle and aircraft maintenance).

Importantly, in many industries the new product development, commercialisation and, importantly, re-certification could take longer than 13.5 years. For example, in the aviation industry all materials/formulations/equipment require extensive review, testing, and approval by all aircraft manufacturers and certification authorities. Historically, this process is very lengthy for the aviation industry often taking over 20-30 years where potential alternatives are not readily available.[14]

It is important to stress that the proposed ban on non-flammable HFO propellants in technical aerosol applications would not only trigger lengthy R&D and re-certification procedures but also considerably impact passenger safety throughout all transportation sectors (aviation, maritime, rail, etc.).

In these circumstances, the introduction of the proposed REACH restriction (i.e., total ban in 13.5 years after EiF) for HFO-1234ze(E) uses in technical aerosols applications is not justified under Articles 68 and 69 of the REACH Regulation, clearly disproportionate with any alleged risk from persistency of TFA and will result in very high costs on the society.

Honeywell submits that fluorinated gas HFO-1234ze(E) must be excluded from the scope of the Proposal. Alternatively, its uses as propellants in technical aerosols applications should be subject to the following time-unlimited derogation in line with unlimited derogations already provided in the Proposal, i.e., new point 4.d of the Proposed restriction - Annex XVII entry PFASs:

"Propellants for technical aerosols in applications where non-flammability and high technical performance of spray quality are required."

1. Introduction

Honeywell is a global manufacturer and supplier of various fluorinated substances, including hydrofluorocarbons (HFC) and hydrofluoroolefins (HFO) gasses. Among these substances is the gas HFO-1234ze(E)[15] which is widely used as propellants in technical and industrial aerosols applications, including as dust removal sprays in various industries (semiconductors an automotive manufacturing, train maintenance, etc.), as disinfectant sprays to prevent the spread of illnesses like malaria, zika or chikungunya (e.g., in aircrafts or trains), lubricants, novelty sprays or ones to test smoke detectors, and others.

Below Honeywell provides information justifying that the substance HFO-1234ze(E) should be excluded from the scope of potential PFAS restrictions due to the absence of unacceptable and not adequately controlled risks within the meaning of Article 68-69 REACH. Alternatively, it should be made subject to unlimited derogation due to the absence of alternatives even in the long term, as explained below.

2. Hazard, exposure and risk assessments of HFO-1234ze(E)

2.1. Flammability assessments

In this respect, contrary to the information provided on page 245, Annex E.2.8 of the Proposal, suggesting that *"HFO-1234ze has been found to be a highly flammable gas in combustion experiments"*, Honeywell submits that this allegation is not correct as far as HFO-1234ze(E) uses as refrigerants and/or propellants in technical aerosols applications are concerned. This substance was comprehensively tested for such uses in accordance with the Council Regulation (EC) No 440/2008 of 30 May 2008 (Method A.11), PED, GHS, DOT, IATA, and IMDG rules and found to be non-flammable even when sprayed directly into a flame source or in confined spaces (please see respective assessment in **Annexes II-V** below). This conclusion is reflected in the REACH registration dossier and CLP classification of HFO-1234ze(E).

[14] See e.g. Figure 1 in *Aerospace & Defence Qualification Process Impacts on Ability to Substitute Cr(VI) Substances*, ADCR Consortium.

[15] 1-Propene, 1,3,3,3-tetrafluoro-, EC no: 471-480-0, CAS no.: 1645-83-6, Mol. formula: C3H2F4

2.2. Objective assessments of HFO-1234ze(E) and its degradation products

In section 1.1.6 of the Proposal the Dossier Submitters concluded that *"all PFAS" (i.e., as a group)* should *"be treated as non-threshold substances for the purposes of risk assessment in a similar manner to PBT/vPVB substances"* and that any of their releases *"can be used as a proxy for risk"*. This conclusion is manifestly incorrect as far as HFO-1234ze(E) and its atmospheric degradation product trifluoroacetic acid (TFA) are concerned.

- **Unjustified grouping of "all PFAS"**

Grouping of HFO-1234ze(E) with *"all other PFAS"* is not scientifically and legally justified. In this regard, the 2021 OECD's PFAS definition used in the Proposal 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 hazards of substances, even regarding their very persistent (vP) properties, or uses, exposure and risks.[16] In other words, the OECD itself is clear that its definition of PFAS was not intended 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) [17] service and US Environmental Protection Agency (EPA) [18] share the same opinion.

The most recent EEAP 2022 Assessment Report[19], 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"*.[20] The Report further 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"* [21]

Please refer on the inconsistency of grouping methodologies in the Proposal to relevant sections of Honeywell submission reference no: bb6e00b6-571b-467a-ae79-7b046c6c9ab4.

- **Hazard and risk assessments of HFO-1234ze(E) and TFA**

Contrary to what the Dossier Submitters claim, there are a range of PFAS substances, including HFO-1234ze(E) and certain other fluorinated HFC/HFO gases that are low-hazardous, have low-Global

---

16 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 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."*

17 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."*

18 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."*

19 *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

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

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

Warming Potential (GWP), not (v-)persistent (not P/vP) and do not degrade to vP substances in meaningful amounts. For instance, the REACH registration dossier and Chemical Safety Report (CSR) for the fluorinated gas HFO-1234ze(E) contains conclusive scientific evidence demonstrating that this substance is not persistent and does not exhibit risks similar to PBT/vPvB substances under Article XIII REACH. Its REACH registration dossier also does not demonstrate an existence of any "*supporting concerns"* or hazards assessed in section 1.1.4. of the Proposal, including bioaccumulation, mobility, long range transport potential (LRTP), accumulation in plants, global warming potential (GWP), endocrine or (eco)toxicological effects, etc.

Therefore, the conclusions of the Dossier Submitters in section 1.1.6 of the Proposal, that HFO-1234ze(E) must be treated as a *"non-threshold substances"* with the overall concern *"very similar to those of the PBT/vPvB substances"* are not substantiated. [22]

In the meantime, according to the trifluoroacetic acid (TFA) [23] REACH registration dossier and CSR, this substance also 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.[24] In this respect, ECHA already reviewed/evaluated the TFA dossier without concluding that further regulatory actions were needed.[25]

For detailed information and objective assessments of TFA, please refer to the previous Honeywell submission no: 76bb3d12-2101-4390-82cf-3498b47e8015.

Regarding, exposure to HFO-1234ze(E) and TFA, even if one would assume that TFA formation yield for HFO-1234ze(E) can reach over 2% as suggested at page 50, Annex B of the Proposal, its contribution to overall tonnages/emissions[26] and concentrations of TFA would remain genuinely negligible.[27]

In this respect, Q&A 10 of Addendum to the EEAP 2022 Assessment Report confirms that "*However, for lakes and oceans, the effects of increased concentrations of naturally occurring mineral salts, such as sodium chloride, and other water-soluble minerals are greater and more biologically significant than those caused by TFA salts. Salts of TFA in soil are taken up by plant roots and concentrate in the leaves, where they appear to have no effects. If animals eat the leaves, TFA is rapidly excreted and does not accumulate in their bodies or in the food chain."* [28]

And further the EEAP concluded that *"Based on current knowledge, [HFC/HFO] breakdown products do not pose environmental concerns. Based on estimates of current and future use of HFCs and other replacements for CFCs, additional inputs of TFA to the ocean will only slightly (less than 0.5% per year) increase the amounts that have been present historically. Now and in the distant future, predicted TFA concentrations in surface waters and terminal basins are thousands of times less than thresholds of concern for human or environmental health."* [29]

---

22 See analysis and conclusions of section 1.1.6 (Risk characterisation) of the Proposal.

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

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

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

26 See Fig. 12 at page 282 (Estimated Global Emissions) in the *Environmental Effects of Stratospheric Ozone Depletion, UV Radiation, and Interactions with Climate Change*, EEAP 2022 Assessment Report.

27 Please see the Honeywell submission reference no 76bb3d12-2101-4390-82cf-3498b47e8015.

28 Please also see, Q&A 10, *Questions and Answers about the Effects of Ozone Depletion, UV Radiation, and Climate on Humans and the Environment*, EEAP 2022 Assessment Report.

29 *Ibid.*

There is also solid scientific experimental and modelling body demonstrating that atmospheric decomposition of HFO-1234ze(E) does not result in formation high-GWP substances like HFC-23 (CF3H).[30]

Therefore, HFO-1234ze(E) and TFA should not be treated as "*non-threshold substances"* and *"any of their emissions"* should not be used *"as a proxy for risk"* for exposure and risk characterisation purposes of REACH restrictions. The corresponding health and environmental risks from HFO-1234ze(E) in technical aerosols applications could not be legitimately considered as unacceptable within the meaning of Article 68 REACH or to any extent proportional to the ban on this substance envisaged in the Proposal.

2.3. Existing effective risks management options (RMO)

HFO-1234ze(E) does not exhibit and is not classified for any environmental hazard. Furthermore, human exposure of this substance was comprehensively tested and approved in accordance with strict pharmaceutical regulations in EU and worldwide (US, Japan, ect.). For instance, for uses as propellants in pressured Metered Dose Inhalers (pMDI) under Medical Devices Regulation (MDR)[31], rules and procedures of European Medicines Agency (EMA) as well as relevant provisions of other EU medicines and veterinary laws.[32]

In addition, HFO-1234ze(E) as a propellant in technical aerosols is subject to rigorous risk management measures provided under *EU F-Gas Regulation* , *Biocidal Products Regulation (BPR)*[33] (for e.g. disinfectants) and in relevant industry standards, including in aviation, space[34] and various others.

Considering that all emissions of propellants occur at the use stage, all respective risks are already adequately controlled and the proposed REACH restriction (i.e., ban) is disproportionate and excessive within the meaning of Articles 68 and 69 REACH resulting in a *"double regulation"*.

In the current Proposal, the Dossier Submitters also applied the same assessment approach to the regulation of PFAS as active substances in biocidal, plant protection and pharmaceutical products. In Honeywell's view, the use of HFO-1234ze(E) as a propellant in technical aerosols applications should be either completely excluded or made subject to a time-unlimited derogation from the PFAS restriction in question.

3. Assessments of alternatives

Upon phasing down and substitution of HFC under the EU F-Gas Regulation, HFO-1234ze is the sole remaining non-flammable liquefied gas propellant available to the technical aerosol industry.

As correctly highlighted in sections E.2.8 and E.2.8.2.5. of Annex E of the Proposal all potential alternatives to HFO-1234ze(E) are not suitable for applications in technical aerosols for various reasons.

---

30 See a summary *A new study demonstrates that HFC-23 (CF3H) is not formed during the decomposition of HFOs and HCFOs in the troposphere*, 04 February 2022; and *Refrigerant Degradation: Is HFC-23 (CF3H) formed due to the decomposition of HFOs and HCFOs in the troposphere?*, 03 June 2021; also *Tropospheric photolysis of CF3CHO*, Mads Peter Sulbaek Andersen, Ole John Nielsen, March 2022.

31 *Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC*. (Medical Devices Regulation or MDR)

32 According to Article1.9 of the Medical Devices Regulation (MDR), IMD propellants form a *"single integral product"* with the administered medicinal product and thus are also governed by the relevant provisions 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, Regulation (EU) 2019/6), including EMA or national marketing authorization requirements/procedures.

33 Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products.

34 See e.g., NASA Technical standard NASA-STD-6001 on flammability testing.

For instance, HFC-32 (Difluoromethane) is flammable F-gas with GWP of 771 against 1.37 of HFO-1234ze(E)[35]. The same is true for other HFC gases, such as HFC-134a and HFC-152a. These are clearly *"regrettable substitutions"* in applications in question. Generally, according to the Montreal Protocol, Kagali Amendment and *EU F-Gas Regulation*, its uses should be phased down by 2030 via progressively decreasing volumes of permitted quotas.[36]

Nitrous oxide is also a flammable oxidiser which could be used as a recreational drug and has serious health side effects.

Other potential substitutes are all hydrocarbons with important flammability risks that cannot be used in many industries (e.g., aerospace, maritime, etc.). They are often classified as extremely flammable gases resulting in significant safety issues from both manufacturing perspective and use.

Not-in-kind alternatives (incl. compressed other gases) have inferior spray quality and are not appropriate for many applications e.g., where the propellant also acts as a solvent or the payload.

Therefore, for many technical aerosols there are no non-flammable alternatives to HFO-1234ze(E) which can guarantee non-flammability and ensure comparable product performance.

For instance, aerosols used for the disinfection of aircrafts must be non-flammable but also follow other requirements from several international recommendations, standards and regulations (WHO, ICAO, Boeing/Airbus). This also concerns aerosol dispensers for testing fire detectors at homes, offices, hotels, restaurants., etc.

Moreover, liquefied gas aerosol propellants for dust cleaning during the operation (power-on) of electrical and electronic equipment must be non-flammable and with high dielectric characteristics (constant, i.e. non-conductive) - only HFO-1234ze(E) satisfies both the requirements.[37] Non-flammable aerosols are also important multipurpose lubricants in anti-seize applications on electronics or electromechanical assemblies that cannot be switched off during cleaning. Non-flammability is crucial for aerosols used for cleaning of large isolating surfaces or in their neighbourhood that can get high electrostatic charging (e.g., contact cleaners).[38]

The same is true for aerosols dispensers for cleaning of medical and anaesthetic devices providing oxygen and nitrous oxide (NO) treatments (e.g., asthma, COVID-19, neonates with respiratory failure). For instance, in medical anaesthetic gas applications, only fluorinated gases enable conformance to the technical specifications under ISO 80601-2-55 standards.[39]

HFO-1234ze(E) based aerosols are used as solvents because they need to be non-flammable and non-combustible and have required solubility/miscibility characteristics.

Compressed gas propellants or not-in-kind alternatives technologies, such as bag-on-valve, cannot be used due to significant deterioration of performance.[40]

Entry 40 of Annex XVII to REACH also prohibits the use of flammable substances in *"aerosol generators placed on the market for the general public for entertainment and decorative purposes"* (so-called novelty sprays).

---

35 See Table 7.SM.6 at pages 17-18 of *The Earth's Energy Budget, Climate Feedbacks and Climate Sensitivity Supplementary Material,* IPCC AR6 Report, 2021.

36 See Annex I of the *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.*

37 See e.g., Study of the dielectric properties of HFO gas, and its application to reduce the environmental impact of medium-voltage systems, Simon Souli, Université Grenoble Alpes, 2021.

38 On importance of non-flammable aerosol contact cleaners see e.g. here.

39 ISO 80601-2-55:2018, Medical electrical equipment — Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors.

40 See e.g. on the loss of performance of compressed gas propellants at page 2 of the *Committee of Experts on the Transport of Dangerous Goods and on the Globally Harmonized System of Classification and Labelling of Chemicals*, UN/SCETDG/56/INF.9, 5 November 2019.

Signal horns used on ships and boats and other places for safety reasons are also niche applications that must only use non-flammable aerosols due to the place (e.g., marine pleasure craft) or conditions (risks of fire or other sources of ignition) during use. The use of non-flammable aerosols for marine uses are due to safety concerns around having flammable sources aboard a marine craft.

The change in propellants in aerosol dispensers also impacts many elements of the supply chain of formulations and production of devices/equipment, including seals, cans, valves, etc. Many of these must be tested and/or redesigned with the new propellant for compatibility and final product tested for leachables. New manufacturing equipment must be developed and built to adapt to the characteristics of any new medical propellants (e.g., flammability). It is also important to understand that these changes involve regulatory assessment, and depend on regulatory approval, from national regulatory authorities.

For example, in aviation industry all materials/formulations/equipment require extensive review, testing, and approval by all aircraft manufacturers and certification authorities. Historically, this process is very lengthy for the aviation industry and could take over 20-30 years.[41]

In these circumstances, the introduction of the proposed REACH restriction (i.e., total ban in 13.5 years after EiF) for HFO-1234ze(E) uses in technical aerosols applications is not justified under Articles 69 and 69 of the REACH Regulation, clearly disproportionate with any alleged risk from persistency of TFA and will result in very high costs on the society (see section 4 below).

Therefore, *"Careful and impartial"* analysis of all available information[42] on the safety, health and environmental properties as well as applicable legal and regulatory requirements on alternatives suggests that HFO-1234ze(E) propellants in technical aerosols must be either excluded from the potential PFAS restriction or made subject to time-unlimited derogation.

4. Disproportionality of the proposed REACH restriction

Reporting of HFC (including, HFO-1234ze(E) propellants) is mandatory under the *EU F-Gas Regulation*. According to the European Environment Agency (EEA) statistics extracted from the *Annual European Union greenhouse gas inventory 1990–2021 and inventory report 2023, c*ombined 2021 HFCs emissions from *Aerosols/Metered Dose Inhalers* (section 2.F.4) in the EU-27 represents 1 620 kt CO_2 eq.

The HFC reported in section 2.F.4, include HFC-134a (in medical and technical aerosols), HFC-227ea (medical aerosols only) and HFC-152a (technical and medical aerosols).

However, for technical aerosols and associated aerosols, the EU industry has already shifted from the use of HFC-134a and HFC-152a to HFO-1234ze and to other solutions wherever possible due to limitations/quotas under *EU F-Gas Regulation.* This is due to the prohibition of HFCs in aerosol applications.

European Aerosol Association (FEA) estimates the quantities of HFO-1234ze(E) in non-pharmaceutical aerosols ("*Aerosols*" under 2.F.4) below 1 500 tons per year.[43] Honeywell agrees with these estimates. Considering that TFA yields for HFO-1234ze(E) are only 2%[44], this would result in annual TFA

[41] See e.g. Figure 1 in *Aerospace & Defence Qualification Process Impacts on Ability to Substitute Cr(VI) Substances*, ADCR Consortium

[42] I.e., under the EU general principle of good administration, *Jean-Louis Burban v European Parliament*, case C-255/90 P; *Detlef Nolle v. Council of the European Union*, case T-167/94; *Przedsiębiorstwo Energetyki Cieplnej sp. z o.o. v ECHA*, case T-625/16, para. 89; BASF and REACH & colours v ECHA, case T-806/17, para. 75; *Technische Universität München v Hauptzollamt München-Mitte*, case C-269/90, para. 14.

[43] See FEA submission within this consultation on the Proposal.

[44] See Fig. 12 at page 282 and sections SI 4.3.2 at page 317 of the of the *Environmental Effects of Stratospheric Ozone Depletion, UV Radiation, and Interactions with Climate Change*, EEAP 2022 Assessment Report.

environmental emissions of 30 tonnes only. These are truly negligible tonnages vis-à-vis total TFA tonnages and concentrations (pre-)existing and projected in the environment (see section 2.2 above).

Moreover, it is important to stress again that the ban on non-flammable HFO propellants in technical aerosol applications envisaged in the Proposal would not only trigger lengthy R&D and re-certification procedures but also considerably impact passenger safety throughout all transportation sectors (aviation, maritime, rail, etc.).

It is beyond any doubts that the alleged risks from the above TFA emissions are incomparable with the heavy costs on the society inevitable upon the implementation of the risks management options envisaged in PFAS restrictions Proposal. It is particularly true for safety and lifesaving applications assessed in section 3 above.

5. Conclusions

Honeywell urge ECHA to *"carefully and impartially"* asses all available information on safety, health and environmental properties of HFO-1234ze(E), TFA and potential alternatives as well as applicable legal and regulatory requirements and existing risk management options beyond the Proposal.

Considering all the above, Honeywell submits that fluorinated gas **HFO-1234ze(E)** used as a **propellant in technical aerosols** must be **excluded** from the scope of the Proposal or made subject to the following **unlimited derogation**: *"Propellants for technical aerosols in applications where non-flammability and high technical performance of spray quality are required."*

Annex I - *List of acronyms and abbreviations*

Annex II - *Conversion Manual Chapter 3: Flammability Assessment*

Annex III – *Flammable and Explosive properties of HFO-1234ze*

Annex IV - *Endpoint study record: Flammability HFO-1234ze MA-RR-09-4278*

Annex V – *Honeywell Statement on Solstice® HFO-1234ze(E) Refrigerant under PED*