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

Honeywell Europe N.V.
Hermeslaan 1H
B-1831 Diegem
www.honeywell.com

Uses of Honeywell Fluorinated Products in the EU

Cover Note for the 2nd Stakeholder Consultation on a Restriction for PFAS

15 October 2021

Honeywell welcomes the chance to respond to the *Questionnaire* within the *2nd Stakeholder Consultation on a Restriction for PFAS*. This note intends to supplement our response providing more context on certain refrigerant and blowing agents uses in the EU and laying out the consequences of a future potential restriction. We also aim to enhance information in the corresponding summary reports/studies ("Summary Reports") accompanying this consultation.[1]

In addition, while we are aware that this questionnaire is not directly about the definition, we wish to repeat that we disagree with the inclusions of HFOs, HFCs and their blends in the RoI PFAS definition and our submission must be read with this point as a backdrop.

We disagree with the inclusion of thousands of substances many of which have unique characteristics and contributions to society. Attempting to regulate all such substances as one group, based only on structural characteristics and ongoing risk assessment studies for compounds that represent <1% of such substances, is not scientifically justified nor appropriate to guide effective regulation. Such an attempt ignores the chemically diverse properties/attributes found among similarly defined substances. Fluorinated compounds like HFOs, HFCs are not persistent, not bio accumulative, nor toxic. HFOs have been vetted and approved as safe alternatives by regulatory bodies in countries around the world. HFCs have also been vetted as safe, but they are being phased down globally under the Kigali Amendment.

1. Introduction

Honeywell International Inc. ("Honeywell") is a global manufacturer and importer into the European Union ("EU") of various fluorinated products solutions, including hydrofluorocarbons ("HFC") and hydrofluoroolefins ("HFO") refrigerants and their mixtures ("blends"). The company offers these products in the EU and worldwide principally under the trademark Solstice.[2]

We believe that information and analysis as presented in the Summary Reports relevant for fluorinated refrigerants ("F-gases")[3] appears too generic and therefore could be perceived, in several places, to be unreliable and incomplete.

[1] *Notice on 2nd Stakeholder Consultation on a Restriction for PFAS* - https://www.reach-clp-biozid-helpdesk.de/SharedDocs/Downloads/DE/REACH/Verfahren/Beschr%C3%A4nkung/Consultation-PFAS.pdf?__blob=publicationFile&v=3

[2] The full list of products and technical and physico-chemical specifications of Honeywell refrigerants are available at - Product Catalogue | European Refrigerants (honeywell-refrigerants.com).

[3] See *Report for Project on PFAS-based Fluorinated Gases (F-gases) Used as Refrigerants or in other Applications,* Report *Summary F-gas uses - Heating, ventilation, and air conditioning and refrigeration (HVACR), foam-blowing agents, solvents, propellants, cover gases and fire suppressants, Report summary PFAS and PFAS polymer production* and *Report summary Transportation* accompanying this stakeholder consultation.

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Given the diverse physico-chemical properties (incl. hazardous profiles) and multi-sectoral uses of F-gases, a substance-by-substance analysis as well as application-by-application assessment of their uses and of available alternatives is required/mandated by REACH. We are concerned from the two F-gases use Summary Reports and single reports on production and transportation shared that such an analysis had not been done yet. Below, we cover some missing elements we believe must be considered.

2. Refrigerants market in the EU

According to the industry data available to EFCTC (Cefic) and Honeywell, information on tonnages, emissions and trends of uses of fluorinated products provided in two F-Gases, Transportation and PFAS Production Summary Reports is not recognisable to us, and we cannot therefore confirm it is accurate.

3. Information on specific uses/sectors

Honeywell agrees with certain conclusions in the Summary Reports on the absence of alternatives to fluorinated refrigerants in several industry sectors (e.g., electronics, data centres, solvents) and provides the following additional information on certain other applications of F-gases. We further observe that the analysis of available alternatives and impacts of potential substitutions (SEA) for certain key uses (i.e. MAC, foam blowing agents) appears biased, incomplete and misleading.

3.1. Commercial refrigeration

Taking into account toxic properties of ammonia (NH3, R-717) and high flammability of hydrocarbons (HC), their use as refrigerants in the commercial chillers/refrigerators sector (i.e., supermarkets and large retailer shops, with high refrigerants loads) elevates health and safety risks that are incomparable with any alleged risks of fluorinated refrigerants. This contrasts with the equivalent risk for HFOs (e.g., HFO-1234yf/ze) and low Global Warming Potential (low-GWP) HFC/HFO/HCFC blends are concerned.[4]

Modern HFO/HFC (e.g., HFO-1234ze) based Heat Ventilation Air Conditioning ("HVAC") and refrigeration systems for large supermarkets/shopping malls provide full coverage of refrigeration, heating, AC and hot water needs of premises/buildings. Use of these refrigerants ensure simplicity and maximum efficiency (+5-10% energy efficiency and 20-30% reduced electricity consumption) for large centralised systems in comparison with any other refrigerants.[5] In the meantime, high working pressure (x10 times), fugitivity and poor performance in hot climates of CO2 (R-744) refrigerant makes its uses in small/mid-size commercial chillers/refrigerators inefficient, high energy consuming (impacts the EU Green Deal objectives) and expensive for maintenance, particularly in Southern Europe and in small private shops (SMEs). Replacement of existing HFO/HFC chillers/refrigerators in private retail will substantially elevate costs of SMEs business. Increasing global warming considerably aggravates the above problems. Various tools (includinng Honeywell's EcoEfficiency Calculator) have shown the significant energy savings possible with HFO solutions.

3.2. Industrial refrigeration

[4] See in more details on benefits of HFO refrigeration and cooling systems in the Honeywell presentation *Long-Term Refrigerant Solutions and Sustainable Architectures for Refrigeration Systems* - *https://www.honeywell-refrigerants.com/europe/wp-content/uploads/2018/12/Chillventa-2018-_Long-Term-Refrigerant-Solutions-and-Sustainable-Archite.…pdf*

[5] See at pages *9-11* in *Long-Term Refrigerant Solutions and Sustainable Architectures for Refrigeration Systems* - https://www.honeywell-refrigerants.com/europe/wp-content/uploads/2018/12/Chillventa-2018-_Long-Term-Refrigerant-Solutions-and-Sustainable-Archite pdf

New generation of HFO refrigerants (such as HFO-1234ze) ensure substantial reductions (by over 88%) in total life cycle costs of industrial water, air and centrifugal chillers in comparison with ammonia (NH3, R-717) systems. Considering high overall value/price of large industrial refrigeration equipment, the above savings are very important. Moreover, substantial energy/electricity savings (70% of a building electricity use is for cooling), due to use of HFO refrigerants, contribute considerably to EU Green Deal (decarbonization) objectives.

For instance, Zimavi Vegetable Processing project (Alicante, Spain) or Quercy Fruit storage and processing project (South-West France) reached better safety/health risk management and 70% lower operational costs (including energy/electricity use) than a corresponding R-717 installation.[6]

3.3. Heat pumps

HFO-1234ze and HFO-1233zd refrigerants, which are not persistent, are already used in many large-scale and essential infrastructural projects in Europe. For example, in city district heating via data centres cooling and heat recovery (Geneva, Switzerland), in sea water based heating and cooling district system (Rolfsbukta, Norway), in Copenhagen Airport (up-to 10% energy savings), in EUROCONTROL data-centre colling system (12%+ reduced energy consumption), in Bäcker Feihl/IceCool plant (Germany) and in many others.

There are no technical possibilities for refrigerant replacement in these long-term high-scale economic and social value projects. Potential REACH restrictions on HFO/HFC refrigerants would affect their supply and put in danger, these otherwise successful projects. The widespread use of natural refrigerants (including ammonia, hydrocarbons and CO2) as an alternative in heat pumps cannot currently replace the use of HFOs for technical reasons due to safety (including flammability) requirements and the desired efficiency requirements.

In addition, as noted by *The Federation of German Industries* (BDI), in order to achieve the EU climate targets, the switch from fossil fuels to electrical-driven heat pumps is one of the decisive measures to decarbonize heating. The Heating and Cooling (H&C) sector accounts for roughly half of the energy consumption in Europe. Currently, 75% of the energy used for H&C comes from fossil fuel.

In recent years there has been a massive conversion of heat-pumps components and equipment concepts to new HFOs to achieve this. Additional restrictions on the use of HFO refrigerants via PFAS regulation would make it impossible to achieve the EU climate targets for 2030 especially considering growing needs link to inter alia the planned renovation wave in the EU.[7]

3.4. Transport refrigeration (all means of transport)

Use of CO_2 systems in the transport refrigeration sector (by roads, railways, sea, rivers, planes) is highly limited due to layout of existing trucks/vessels prescribed by relevant safety specifications of vehicles/containers/etc. Use of hydrocarbons considerably elevates flammability and safety risks for the road and other means of transport. In the meantime, large loads of toxic ammonia in refrigeration systems of commercial tracks/containers lead to high exposure and health risks of drivers, warehouse workers and general population.

Only HFO/HFC based refrigeration provide the characteristics required by respective international and national technical standards. The switch to other refrigerants would require amendments of relevant regulations/standards, including at the international level. Otherwise, international transportation of EU

[6] *Ibid.*, pages 13-15

[7] See at pages 19-21 of the BDI position on *EU chemicals legislation: Restriction of PFAS, Evaluation of the envisaged restriction procedure* - https://bdi.eu/publikation/news/eu-chemikalienrecht-beschraenkung-von-pfas/

vehicles/containers with alternative refrigeration systems will be at risk. In this case, the resulting, inevitable disruptions on international trade and supply chains of many goods should not be underestimated.

3.5. Mobile Air Condition (MAC) and heating

The analysis of refrigerants uses in MAC applications in relevant Summary Reports on F-gases and Transportation is biased and appears to justify, by all means, REACH restrictions on HFO-1234yf in favour of CO_2 (R-744) alternatives. In practice HFO-1234yf (R-1234yf) is *"the refrigerant of choice"* of the automotive industry worldwide. For the sake of objectivity, a detailed standalone ***Information Note*** from the standpoint of automotive manufacturing sector is enclosed to this Cover Note. This document provides detailed

discussions on relevant features of HFO-234yf and alternatives, including on specifics of Electric Vehicles. In addition:

- the estimate of additional cost of €300/vehicle for adoption of CO_2 MAC systems provided in the Summary Report on F-gas uses[8] is not correct because this amount only comprises the cost of MAC system as such (hardware) and does not consider additional maintenance (possession costs) and energy/fuel costs over all lifecycle of the vehicle. The difference could be considerable in hot climates where CO_2 MAC equipment poorly performs and requires more energy.
- The indicative benchmarking methodology (i.e., Oosterhuis, 2017) used in Table 2 of the above F-gas Summary Report is not appropriate. This methodology is purely statistical. It is based on average figures from previous ECHA's experience on restrictions. [9] It is not intended to consider complex situations where large groups of very different substances and multisectoral uses of many refrigerants need to be assessed, such as in case of potential restrictions on PFAS.
  Moreover, the proposed methodology presumes the leakage of a full quantity of F-gas refrigerant during the lifecycle of vehicles. This is not correct because annual leakage rates of modern HFO MAC systems is lower than 7% and remaining substance is recuperated at the end-of-life of the system. In the meantime, due to 10 times superior pressure, even small defects of CO_2 MACs almost immediately lead to release of the full CO_2 load inside and/or outside the vehicle. Therefore, CO_2 MAC systems will require much frequent control checks and maintenance leading to higher possession costs that are not considered in the proposed methodology.

Other important features of refrigerants applications in automotive MAC, HVAC and Thermal Management Systems (TMS) in Electronic Vehicles are discussed in the enclosed Information Note.

3.6. Foam Blowing Agents

Currently, the most used by the foam blowing industry replacements of HFCs are HFO-1336mzz(Z) (CAS: 692-49-9), HCFO-1233zd(E) (CAS:102687-65-0) and HFO-1234ze(E) (CAS:29118-24-9). All of them have

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[8] Table 2 of the Report Summary F-gas uses - Heating, ventilation, and air conditioning and refrigeration (HVACR), foam-blowing agents, solvents, propellants, cover gases and fire suppressants.

[9] A benchmark-level approach for evaluating PBT and vPvB chemicals in REACH authorisation and restriction procedures, Silke Gabbert, Stefan Hahn, Michael Klein, Monika Nendza, F.H. Oosterhuis, 2017. I.e. "The study concludes that, although cost estimates of previously adopted actions do not allow deriving a value for society's willingness to pay to reduce PBT presence, use, and emissions, roughly speaking, the available evidence suggested that measures costing less than €1 000 per kilogram PBT use or emission reduction would usually not be rejected for reasons of disproportionate costs, whereas for measures with costs above €50 000 per kilogram PBT such a rejection is likely".

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superior safety (flammability) and insulation (thermal conductivity) characteristics in comparison to any other potential alternative, while being much less expensive.

The above non-hazardous substances have short atmospheric life (ca. 26 days) and low-GWP (below 5). They do not degrade to PFAS in meaningful quantities (maximum theoretical yield rate to the naturally occurring substance TFA is 2-4%)**10** and are only used within the foam insulation industry in gaseous forms (i.e., no risk of water or soil contamination as well as low end-life risks). REACH restrictions covering these substances are therefore not justified on legal, scientific and practical grounds.

For more detailed information, please see **PU Europe's** (www.pu-europe.eu) response to this stakeholder consultation. Honeywell is a member of this association.

4. The consequences of potential Restriction

The current RMM regulatory measures provided in the EU F-Gas Regulation (EU) No 517/2014 specify a timetable for phasing-out F-gases with high GWP by 2030. The required investments and planning have been already made by producers and down-stream users of F-gases equipment considering this timetable. Any prohibition of HFCs will cause a complete disruption of the transition from higher-GWP products (HCFC/HFC) and would likely undermine and impede the EU Green Deal ambitions.

The parallel ban of HFOs, which are widely considered as the most viable alternatives to HFC (including in the Summary Report on PFAS production), will certainly lead to grave consequences for daily lives of most people. For example:

- The obsolesce of hundreds of millions of existing Refrigeration, Air conditioning and Heat Pump systems including car, van and truck Air Conditioning systems when maintenance or servicing is required due to unavailability of refrigerants
- Existing standards, regulations and codes impose constraints on location and charge size for all refrigerants, constraining systems and performance in the absence of F-gases. Some current designs are impractical without F-gases
- No high-performance non-flammable blowing agent for insulation spray foam
- No more metered dose inhalers (MDIs) used in treatments for conditions including asthma and COPD, as they use F-gases

The expected reality is that existing HFC/HFO equipment would be forced to come to the end of its service life before non-F-gas systems may be developed and adopted. For small appliances and vehicles this may be a period of 10-15 years whilst for some industrial, commercial and essential infrastructure applications it may take much longer, i.e. over 40 years (see Sections 2.2 and 2.3 above). In the case of shorter periods economic and social consequences would be even difficult to imagine.

The market moves towards alternatives whenever this is possible from a safety, energy efficiency and affordability perspective taking into account environmental concerns, which are often already reflected in relevant industry standards/specifications and statutory RMM. A ban of F-gases would immediately act against this and have a heavy impact.

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[10] E.g., see on HCFO-1233zd-E at *Experimental results of HFO/HCFO refrigerants in a laboratory scale HTHP with up to 150 °C supply temperature*, 2019 - https://www.ost.ch/fileadmin/dateiliste/3_forschung_dienstleistung/institute/ies/projekte/projekte_tes/91_sccer-eip/arpagaus_and_bertsch_2019_experimental_results_of_hfo_hcfo_refrigerants_in_laboratory_scale_hthp_with_up_to_150_c_supply_temperature.pdf

REACH restrictions on F-gases would also affect the EU's import and export flows. A ban on manufacture, placing on the market and use, this would create difficulties for EU industry to compete on the global export market. It is expected that many leading chemical and equipment producers would relocate their manufacturing plants from EU to third countries.

According to the industry estimates, the prohibition of F-gases in the EU would result in a complete shutdown of the production and distribution of the affected products. This would result in the closure of the manufacturing sites in the EU (costs several € 100s millions). Several hundreds of thousands of jobs would be lost within the production section and a similar number of jobs lost within the distribution sector as, in many cases, distribution for non-fluorinated alternatives is a different model. Recovery for recycling/reclaim of products would cease. Research and development in companies which produce F-gases would also cease with job losses very close to the entry into force of any future legislation.

5 Conclusions

Therefore, Honeywell believes that potential REACH restrictions on the use of HFO/HFC substances in heating, ventilation, air-conditioning (HVAC), refrigeration and foam blowing sectors are not scientifically, legally, and practically justified and would result in disproportionally high costs for the society in comparison to any negligible risks due to alleged persistence in the environment of their decomposition product - TFA.

We remain available to discuss this topic further or respond to any questions/clarification you have on our various submissions

Honeywell Europe N.V.
Hermeslaan 1H
B-1831 Diegem
www.honeywell.com

Use of PCTFE fluoropolymers in Honeywell's Aclar products

Cover Note for the 2nd Stakeholder Consultation on a Restriction for PFAS

15 October 2021

Honeywell welcomes the chance to respond to the Questionnaire within the *2nd Stakeholder Consultation on a Restriction for PFAS*. This Cover Note is intended to supplement this response. One observation we have is that PCTFE fluoropolymers get little to no mention in summary reports/studies ("Summary Reports"). 1 Therefore, Honeywell wishes to take this opportunity to share more context on this fluoropolymer's uses in medicinal/pharmaceutical packaging sectors as authorities work further on the possible future PFAS Restriction report.

In addition, while we are aware that this Questionnaire is not directly intended to address the PFAS definition, we wish to reemphasize our disagreement with the inclusion of PCTFE fluoropolymers into the scope of potential PFAS Restriction report and our submission must be read with this point as a backdrop.

It is well known that PCTFE is inert and not bio accumulative material. PCTFE does not interact with the environment or human or animal organisms. It is approved for use in medical devices and parenteral applications in the Pharmacopeia standards of WHO, in the Europe, US, Japan and in many other jurisdictions worldwide. It is inappropriate to regulate PCTFE based only on its structural similarity with other compounds, neglecting its bio-inertness, unique characteristics and societal benefits.

1. Introduction

Honeywell International Inc. ('Honeywell') is a global manufacturer and importer into the European Union ("EU") of various fluorinated products solutions, including fluoropolymers such as Polychlorotrifluoroethylene (PCTFE, CAS: 9002-83-9, (C2ClF3)n). The company offers these products in the EU and worldwide principally under the trademark Aclar.

- For more than 40 years, Honeywell's Aclar thermoformable films are used in originator and generic pharmaceuticals and animal health primary packaging.
- Aclar films are based on PCTFE fluoropolymer technology. They are crystal clear, biochemically inert, chemical-resistant, non-flammable, and plasticizer- and stabilizer-free. These films can facilitate patient compliance with doctor prescriptions with transparent, portable and patient-friendly pack presentations.

[1] Available at - https://www.reach-clp-biozid-helpdesk.de/SharedDocs/Downloads/DE/REACH/Verfahren/Beschr%C3%A4nkung/Consultation-PFAS.pdf?__blob=publicationFile&v=3

- Aclar fluoropolymers provide the highest moisture barrier when compared to other extrudable thermoplastics films (ETF). These unique characteristics substantially increase stability, storage and shelf life of medicinal products.
- Aclar products do not require the use of additives that may migrate into drug products. This ensures drug product safety, efficacy, and quality. They fully correspond to and are included in the European, United States and many other *Pharmacopeia* standards worldwide.
- Aclar Accel is the trademark of the new line of the Honeywell's fluoropolymer films designed for blister packs laminates of human drugs. Aclar Edge is the new trademark for Aclar fluoropolymers used for bottles and vials in animal health injectables and human oral liquids.

2. EU regulations on packaging of medicinal products

PCTFE-based Aclar 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).

Substances subject to the above regulations are explicitly excluded from the scope of REACH requirements on registration, downstream users, evaluation and authorisation because all components of medicinal products, including packaging/containers, are already subject to comprehensive and strict safety/quality assessment procedures and data requirements, including on traceability and testing of each component. Safety of pharmaceutical packaging for humans, animals, and environment, including its waste stage, is vigorously scrutinised/approved by the European Medicines Agency's ('EMA') and national authorities prior to the marketing authorisation of each drug (including at production and disposal stages).

Aclar materials also comply with the current World Health Organisation ('WHO')[2] and EU *Guideline on Plastic Immediate Packaging Materials*[3]*,* relevant *European Pharmacopoeia Monographs* as well as the Directive 2002/72/EC and Regulation (EU) 10/2011 on plastic foods contact materials.

Moreover, medicinal packaging is subject to the EU regulations on packaging and packaging waste.[4] These laws establish comprehensive requirements on safety and eco-design of packaging materials and their environmentally friendly waste treatment (collection, disposal, recycling, etc.). All medicinal products packaging in the EU shall comply with these rules when produced, placed on the market, used and disposed within the EU.

Therefore, additional regulation and/or restriction on production, placing on the market and use of Aclar products in the pharmaceutical and animal medicine sectors is excessive. These materials are already subject to vigorous risks management measures (RMM) and strict prior

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[3] See *Guidelines on packaging for pharmaceutical products*, WHO Technical Report Series, No. 902, 2002, and at - https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-plastic-immediate-packaging-materials_en.pdf

[4] *Directive 94/62/EC on packaging and packaging waste; Directive 2008/98/EC on waste (Waste Framework Directive)*

marketing authorisation requirements. If warranted, the European Commission can clarify and enhance relevant practices at any time.

3. Information on tonnages and shares of PCTFE (Aclar)

Relevant Summary Reports[5] miss information on the EU production, import and export of PCTFE fluoropolymers as well as on their uses in pharmaceutical products, which is an essential part of any REACH Annex XV Dossier and/or ECHA's risk and socio-economic assessments of potential restrictions on PFAS.

According to own estimates, our total annual import volumes of PCTFE fluoropolymers used in medicinal/pharmaceutical packaging in the EU in 2015-2020 were in average ca. 89 tonnes. In comparison with total volumes of fluoropolymers used in the EU (ca. 65 000 tonnes in 2018),[6] tonnages of PCTFE and Aclar uses in pharmaceutical/medicinal packaging applications in the EU are negligible – 0,001-0,002%.

Taking into account minimal/negligible tonnages and physico-chemical characteristics of PCTFE (Aclar) as being a polymer of low concern (PLC), potential REACH restrictions of their uses in medicinal/pharmaceutical packaging in the EU are disproportionate to any alleged risks.

4. Absence of suitable alternatives

As correctly highlighted in the Section 2.10 of the *Report summary PFAS and PFAS polymer production*, there are few options for alternatives to many substances which could be included in the proposed definition of PFAS and that the particular *"difficult class of materials to substitute are fluoropolymers*" because for many of their applications there are no known alternatives today [7]. These substances are expensive and are only used due to their unique combination of functionalities. Although, various companies made substantial efforts to develop alternatives, including in the pharma industry.

Although primary pharmaceutical packaging is not explicitly mentioned in the above report, this use clearly falls among the above conclusions. PCTFE is used in numerous critical applications and is indispensable in the delivery and preservation of safe pharmaceuticals that benefit a broad range of markets including originator and generic pharmaceuticals, over-the-counter (OTC) pharmaceuticals and animal health packaging. It is used in thousands of oral solid therapies across all therapeutic areas including nervous system, cardiovascular, metabolic, hormonal, antipsychotic, and oncology. PCTFE is categorised as PLC and does not interact with the environment, human or animal organisms.

Unique PCTFE (Aclar) films properties relevant for medicinal packaging are:

- The best moisture barrier of any clear thermoplastic film (highest WVTR protection)

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[5] *Report summary medical devices*, *Report summary food contact materials and packaging*, *Report summary PFAS and PFAS polymer production*.

[6] Based on information in the *Report summary PFAS and PFAS polymer production* - https://www.reach-clp-biozid-helpdesk.de/media/Helpdesk/download/Report%20summary%20production%20july%202021.pdf

[7] See footnote 6 above.

- Bio-chemical inertness (very low leaching/migration)
- Chemical resistance (practically to most chemicals)
- The highest crystal clarity of any thermoforming film on the market (important to patient safety (dosage/timing) and compliance with prescriptions)
- Non-flammability
- Plasticizer-, stabilizer- and additive- free (high quality and safety of drugs)
- Very good machineability (can be used on existing thermoforming lines without retooling)

Moreover, primary packaging of any medicinal product directly affects one of its key properties - *"stability characteristics"* - the extent to which the drug preserves its quality, safety and efficacy throughout its period of storage and use. Stability characteristics are an integral part of marketing authorisation conditions specified by the EMA or national medicines authorities for each pharmaceutical. Changes in these specifications require additional testing and approval by the authorities (see in more details in section 5 below).

None of potential alternatives for transparent blister or other primary medicine packaging could reach properties of PCTFE (Aclar) materials relevant for the stability of drugs. In other words, there are no alternatives for PCTFE based medicines/pharmaceutical packaging that could meet marketing authorisation specifications approved for given drugs packed with the use of PCTFE (Aclar) products.

In addition, there is potential for higher risk of exposure to hazardous substances in alternatives used to meet the high standards of PCTFE fluoropolymers in many applications. This brings higher safety risks, increases in emissions resulting from technical regression, and could put the EU goals for climate and energy at risk. For instance, other plastic materials, e.g. PVC, discharge hydrochloric acid during incineration and thus are more harmful for the environment then PCTFE. Cold form foil, which can achieve the same moisture barrier, is not transparent and increases the packaging size by 55% in comparison with PCTFE (Aclar).

According to Honeywell knowledge, there are no acceptable chemical or functional substitutes to PCTFE films available in the market. Use of substitutes (like PVDC, COC, COP, etc.) will inevitably result in shorter storage and use periods of medicinal products, which are crucial characteristics for many drugs.

5. Consequences of REACH restrictions on PCTFE (Aclar) uses in pharmaceutical packaging

Our overarching concern is that serious drug shortages will happen once this possible PFAS REACH restriction is introduced. There will be an interruption of supply to potentially thousands of medicines registered in PCTFE packaging affecting the lives of patients across the EU.

The costs associated with changes to packaging formats (technology, machinery, tooling, etc.) would be to producers of packaging, pharmaceutical companies and ultimately to patients. If PCTFE materials were to be banned, pharmaceutical producers would be required to find and qualify alternative packaging formats, resulting in additional R&D costs, stability testing, and other regulatory costs for each drug currently packaged in PCTFE materials.

In the meantime, inferior barrier and leaching/migration properties of other packaging materials will decrease quality, storage and use periods of medicinal products as such. This will indirectly affect safety, health and environmental characteristics of medicines as well as will elevate costs on the industry and undermine affordability of medical treatment for patients. These

consequences could have crucial impact on population in specific situations (emergency stocks, highly sensitive formulations, transportation and storage conditions for vaccines, etc.).

For instance, REACH restrictions on PCTFE uses in medicinal packaging (for humans and animals) will require additional *"stability testing"* and approval of changes/variations by EMA/national authorities for each existing drug. This will require substantial time (i.e. long testing periods with regular intermediate controls) as well as considerable human resources and costs to the industry and authorisation authorities. According to available information, costs of "stability testing" for each medicinal product ranges from 100.000 – 500.000 Euro, excluding fees for approval of variations. Those costs will be passed through to patients and public budgets. Redoing stability tests and submitting results to regulatory bodies will take 5-10 years depending on each company's R&D and Regulatory capacity.

In cases where alternative packaging cannot provide satisfactory stability characteristics of pharmaceuticals, changes to drug formulations will have to be made. This will involve considerable costs (potentially millions of Euros for each product) and time needed for R&D and approval (additional analytical and development testing, preparation of valid applications, evaluations by the authorities, etc.). For instance, total time required for development of a new pharmaceutical product may range from 5 to 15 years and marketing authorisation procedures take at least 6-12 months, involving numerous highly qualified specialists. In this respect, PCTFE restrictions will inevitably and considerably increase burden on pharmaceutical companies as well as constraints on EMA/national authorities.

6 Conclusions

The impact of the REACH restriction on PCTFE uses in pharmaceutical sector, but also on medicinal product diversity and innovative capacity of the EU pharmaceutical industry, is difficult to underestimate. This restriction will put in danger real lives, undermine the EU's economic goals, and jeopardise objectives of the EU Green Deal.

In this respect, Honeywell submits that potential REACH restrictions on the use of PCTFE (Aclar) products in pharmaceutical industry would result in disproportionally high costs for the society in comparison with any possible risks due to persistence of these fluoropolymers. The most preoccupying of this possible future restriction would be drug shortages.

Honeywell commits to continue to provide the authorities with full information on safety of its products and calls on the five proposing authorities to undertake rigorous assessments of alternatives and socio-economic impact on the medicines/pharmaceutical sector within the course of preparation of the REACH Annex XV Dossier for PFAS.

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Honeywell

Honeywell Europe N.V.
Hermeslaan 1H
B-1831 Diegem
www.honeywell.com

To: REACH Competent Authorities of the Netherlands, Germany, Denmark, Sweden and Norway preparing a REACH Annex XV Restriction Dossier for PFAS - [redacted]@baua.bund.de

CC: National Institute for Public Health and the Environment (RIVM, The Netherlands) - [redacted]@rivm.nl

Subject: Use of PCTFE fluoropolymers in Honeywell's Aclar products, Cover Note for the 2nd Stakeholder Consultation on a Restriction for PFAS: *Corrigendum*

21 December 2021,

To whom it concerns,

On 17 October 2021, **Honeywell Europe N.V.** (Belgium) submitted to the five EU Member States competent authorities preparing a REACH Restriction Dossier for the group of PFAS replies to the *Questionnaire within the 2nd Stakeholder Consultation on a Restriction for PFAS*.[1]

Inter alia, Honeywell provided replies for questions in **Section B of the Questionnaire** (PFAS production (manufacturing)) in relation to the specific use of **PCTFE fluoropolymers in medicinal/pharmaceutical packaging**, including comments on the respective *Report summary medical devices july 2021.pdf*. Honeywell accompanied the replies by the **Cover Note** - *Use of PCTFE fluoropolymers in Honeywell's Aclar products*.[2]

In particular, in the reply to **Question B1b)** of the Questionnaire Honeywell estimated the total average annual imported volume of PCTFE fluoropolymers used in the medicinal/pharmaceutical packaging in the EU in 2015-2020 at **ca. 89 tonnes** (i.e., around 0,001-0,002 % of total fluoropolymers uses in the EU (**ca. 65 000 tonnes**)[3]. Same estimates were provided in **Section 3** of the Cover Note.

Above estimates are based on assumptions that due to strict regulatory requirements (i.e., EMA, national medicines authorities) and unique properties of Honeywell's Aclar PCTFE materials, imports of Aclar films constitute almost all PCTFE tonnages used in the EU for medicinal/pharmaceutical packaging purposes.

Upon recent internal evaluations, we found that due to general complexities in customs classification/statistics of fluoropolymers the above average import tonnages of Aclar should be adjusted upwards to **ca. 1 000 tonnes**. Therefore, for the sake of full transparency we wish to submit this ***Corrigendum*** amending respective information in the Honeywell's reply to Question B1b) of the Questionnaire and in the above Cover Note accordingly.

Please note that other information, arguments and conclusions in the Honeywell's replies and Cover Note remain the same. In particular, we would like highlight that even considering the updated PCTFE (Aclar) tonnages, their use in pharmaceutical/medicinal packaging in comparison with total volumes of fluoropolymers used in the EU remain truly insignificant **– app. 0,015%** (i.e., 1 000/65 000 tonnes). We believe that considering the polymer of low concern (PLC) properties of PCTFE (Aclar) and their low volumes/exposure, potential REACH restrictions on use of these materials in pharmaceutical/medicinal packaging in the EU are disproportionate to the alleged risks of their persistency. **END**

[1] See at - https://www.reach-clp-biozid-helpdesk.de/SharedDocs/Downloads/DE/REACH/Verfahren/Beschr%C3%A4nkung/Consultation-PFAS.pdf?__blob=publicationFile&v=3

[2] *Use of PCTFE fluoropolymers in Honeywell's Aclar products*, Cover Note for the 2nd Stakeholder Consultation on a Restriction for PFAS, 15 October 2021

[3] Based on information in the *Report summary PFAS and PFAS polymer production* (EU production, plus imports, and minus exports).

Honeywell

Honeywell Europe N.V.
Hermeslaan 1H
B-1831 Diegem
www.honeywell.com

CO2 vs HFO-1234yf Choice

30 September 2021

Executive summary

Refrigerant R-1234yf (HFO-1234yf) is a compound which was specifically designed to avoid the persistence of previous refrigerants with a high Global Warming Potential (GWP) that contribute to climate change. Over 120 million vehicles worldwide are using HFO-1234yf successfully, without issue. It is the ultra-low GWP (<1) refrigerant of choice for much of the global automotive industry.

Although HFO-1234yf can be broadly classified within the same chemical family as other PFAS, a recent Organization for Economic Co-operation and Development (OECD) report emphasizes that the term "PFASs" is a broad, general, non-specific term, which does not inform whether a compound is harmful and is not a basis for regulation. There is solid scientific data confirming *de minimis* effects of the refrigerant and its main atmospheric decomposition product, TFA on health and the environment.

The EU's F-Gas Regulation, MAC Directive as well as SAE and ISO standards already provide for the risk management measures (RMM) for HFO-1234yf. To address any relevant risks, these regulations and technical standards could be tailored further, if warranted.

Affordable and safe transportation is critical for our society. Use of refrigerants in MAC/HVAC and refrigeration systems in vehicles is essential for people health and for safety of passengers and cargo. Effective and efficient refrigerant is indispensable for the proper functioning of Thermal Management Systems (TMS) in Electronic Vehicles (EV).

The only current alternative for MAC/HVAC/TMS is CO_2 which is characterised by much higher risks in terms of safety, health, environment and cost for society. Significantly higher operational pressures (10 times higher) create new safety concerns in use and service of vehicles. CO_2 performance efficiency in hot weather creates concerns for South and Middle Europe, which will increase fuel consumption in traditional vehicles and reduce range in EVs. CO2 based MAC systems are also characterized by significantly higher costs. The overall effect of using CO_2 as a substitute for R-1234yf would be negative for consumers, the economy, GHG emission reduction targets and the aims of the EU Green Deal.

.MAC/HVAC refrigeration systems are essential for occupant health and safety. HFO-1234yf has been successfully used for nearly 10 years providing cooling for both traditional gasoline/diesel vehicles and EV's thermal management systems. The total cost to society of banning or phasing out of HFO-1234yf refrigerant in automotive applications will be very high and will impede the objectives of the EU Green Deal. These consequences are not comparable with any alleged health or environmental risks of HFO-1234yf misclassified in a broad, general, non-specific list of long chain, more concerning compounds.

1. HFO-1234yf is the right choice for an automotive refrigerant

HFO-1234yf is used as the refrigerant of choice by all carmakers producing for Europe and/or North America. It was specifically developed as an alternative (to R-134a (HFC-134a)) low Global Warming Potential (GWP) refrigerant for various automotive applications, including standard Mobile Air-

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Conditioning (MAC) systems and Electric Vehicle (EV) Thermal Management Systems (TMS) which include battery, motor and inverter cooling and heat pumps).

Currently there are more than 120 million vehicles on the road globally using HFO-1234yf with a proven safety and performance record. This number is expected to grow due to the global phase out of high GWP HFC refrigerants (e.g. R-134a) based on the Kigali Amendment to the 1987 Montreal Protocol (implemented in the EU by means of the F-Gas Regulation and MAC Directive).

Transportation is critical in our society. Affordable and safe freedom of movement is among the basic human rights and EU freedoms.[1] Air-conditioning, heating and/or refrigeration in vehicles are essential for the health and safety of people and cargo. Effective and efficient refrigerant is also an enabler for the proper functioning of EVs with regard to cooling the battery, motor and inverter as well as power electronics (TMS). In this respect, refrigerants provide necessary rather than "nice-to-have" functions in EVs that are essential.

HFO-1234yf is misclassified as a PFAS when compared to the persistent more concerning compounds that are being recognized, studied and regulated today. Formally it may fall within certain chemical definitions limited to the structural characteristics of substances, HFO-1234yf was intentionally engineered to breakdown quickly in the atmosphere to avoid the persistence of previous refrigerants with high GWP that contributed to climate change. HFO-1234yf and its breakdown components do not bioaccumulate in nature and human bodies (see details in the **ANNEX** below). Numerous studies have shown HFO-1234yf to be both safe and effective in a widespread use with *de minimis* effects on health and the environment. HFO-1234yf is characterised by its cooling performance similarities to R-134a which allowed carmakers to accelerate conversion to a very low GWP, environmentally friendly refrigerant with low flammability that is also non-ozone depleting,

R-134a and HFO-1234yf are already subject to risk management measures (RMM) under the EU' F-Gas Regulation, MAC Directive as well as SAE and ISO standards that could be tailored further (at EU or MS levels) to address any relevant risks.

Erroneously labelled "natural refrigerants" such as R-744 (CO2), ammonia and hydrocarbons (propane, isobutene, etc.) are manufactured chemical substances with important hazard and exposure characteristics including toxicity, anaesthetic effects and/or high flammability. Substances found in nature or "natural" do not make them safe, effective or more appropriate for automotive MAC use - CO2 is an excellent example.

Major CO2 refrigerant challenges in vehicles are:

- **Pressure** - Very high operational pressures (10 times that of current refrigerants) that require complete redesign and retooling of all major AC components.
- **Safety** - The safety of servicing vehicles with these high pressures increases the likelihood of accidents. Shrapnel and fragmentation of AC components in the event of a collision are also concerning and unproven in the broad market.
- **Reliability** - Retaining CO2 in the refrigerant system is a challenge given the small molecule size and higher pressures needed. More frequent refrigerant servicing may likely be required and can reduce overall efficiency when low charge conditions exist (particularly in EVs).

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1 *"Transport is a fundamental sector for and of the economy"*, Transport in the European Union Current Trends and Issues, March 2019, page 3 - https://ec.europa.eu/transport/sites/default/files/2019-transport-in-the-eu-current-trends-and-issues.pdf

- **Vibration and noise** - Elevated vibration and noise characteristics of CO2 high pressures coupled with reduced dampening of normal rubber based refrigerant hoses may have a significant effect on customer satisfaction.
- **Cost** - Higher costs for both manufacturers and consumers will have a societal impact, based on both economies of scale and premium materials or structural requirements to maintain the higher pressures. According to estimates, R-744 MAC may result in 300 Euro additional manufacturing costs per vehicle.[2] This figure is not correct because this amount only comprises the cost of MAC system as such (hardware) and does not consider additional maintenance (possession costs) and energy/fuel costs over all lifecycle of the vehicle
- **Performance in hot weather -** CO_2 as a refrigerant in automotive MAC/HVAC systems loses efficiency in hot weather conditions which can increase fuel usage (and CO_2 tailpipe emissions) and reduce EV range based on cooling needs. Energy consumption for MAC AC usage has been estimated to be three times higher in hot climates as opposed to more temperate conditions.[3] Given increasing climate temperatures due to global warming this problem will become even more problematic in the near future.
- The above problems make CO_2 technically concerning and economically undesirable to implement in MAC/HVAC systems at the required scale and level of safety. Overall effects of such changes on consumers' satisfaction and GHG emissions also remain highly questionable.

At the other hand, HFO-1234yf MAC systems are well established and have been in use for nearly 10 years. Moreover, enhanced HFO-1234yf heat pumps for EVs TMS using all sources of waste heat do approach the effectiveness of CO_2 in very cold conditions. In addition, these new systems have better efficiency in hot climates and well-established service procedures/equipment with a proven safety record in the field.

To conclude: The total cost to society of banning or phasing out of HFO-1234yf refrigerant in automotive applications will be very high and will impede the objectives of the EU Green Deal. These consequences are not comparable with any alleged health or environmental risks of HFO-1234yf misclassified in a broad, general, non-specific list of more concerning compounds.

2. Additional information/analysis

2.1. Safety, health and environment

HFO-1234yf was originally developed for MAC systems to provide similar performance to R-134a without having to redesign every component while still providing ultra-low GWP to help resolve refrigerant-based climate change concerns.

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2 ECHA Registry of Intentions (RoI), 2 Stakeholder Consultation on a Restriction for PFAS, *Report summary F-gas uses, Heating, ventilation, and air conditioning and refrigeration (HVACR), foam-blowing agents, solvents, propellants, cover gases and fire suppressants*, July 2021, page 13 - https://www.reach-clp-biozid-helpdesk.de/media/Helpdesk/download/Report%20summary%20F%20gas%20uses%20july%202021.pdf

3 Section 6.4 in *Mobile air conditioning: The life-cycle costs and greenhouse-gas benefits of switching to alternative refrigerants and improving system efficiencies, International Council on Clean Transportation*, White paper, 2019 – https://theicct.org/publications/mobile-air-conditioning-cbe-20190308

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Safety and flammability concerns were addressed by automotive manufactures in numerous collaborative studies before widespread production and after nearly 10 years of field use HFO-1234yf can be considered "proven in use" for safety and effectiveness. The relevant studies of the breakdown components of HFO-1234yf clearly demonstrate a *de minimis* impact on health and the environment (see detail in the **ANNEX** below). Moreover, there has not been any scientific data recorded that shows adverse effects of the widespread use of the refrigerant. Therefore, HFO-1234yf is crucial for automotive MAC, and EV TMS applications based on its performance and environmental benefits.

- **Health and safety**

HFO-1234yf is a non-persistent, non-bioaccumulating, low toxicity gas (similar to R-134a) which is used in MAC/refrigeration systems (see the respective REACH registration data - https://echa.europa.eu/registration-dossier/-/registered-dossier/16012).

HFO-1234yf is characterised as being "mildly flammable" (2L) by the globally recognised American Society of Heating and Refrigeration Engineers (ASHRAE) meaning it requires a higher concentration to ignite, has a lower heat of combustion when burned and has a lower burning velocity compared to other flammable refrigerants. HFO-1234yf flammability was intensely studied for automotive use and shown to pose no significant risk to consumers.[4]

From a toxicity standpoint, HFO-1234yf is considered an (A) rated refrigerant for low toxicity. After nearly 10 years in the field with widespread use for the last 8 years, there have been no documented field or service issues with regard to toxicity or flammability of HFO-1234yf.

CO_2 is not flammable and is also considered low toxicity (A) rated by ASHRAE but the refrigerant does have some unique challenges with regard to health and safety. CO_2 refrigerant releases into the passenger compartment were concerning enough for the US EPA to put usage restrictions for leaks based on anaesthetic and health effects of higher concentrations.[6] Moreover, due to significantly higher pressures, CO_2 systems pose additional risks in the case of automotive collisions and service. While automotive manufacturers do an excellent job of managing risks, CO_2 systems have not reached broad market volumes to prove safety in the field. In 2008, the major SAE International study on alternate refrigerants found that R-744 (CO2) automotive AC systems posed greater risks for consumers than HFO- 1234yf and that it also had a greater environmental impact for climate change based on life cycle climate models.[5]

- **Environment**

HFO-1234yf is non-persistent (non-P) in the environment and non-ozone depleting substance (non-ODS) with the GWP below 1, i.e. lower than of CO_2 (at 1).

However, recent media coverage has mistakenly linked perfluoroalkyl substances (PFAS) and short chain perfluoroalkyl carboxylic acids (scPFCAs) to hydrofluorocarbons (HFCs) and HFOs, providing the perception that these fluorocarbon solutions are harmful to the environment, marine life and humans. This is inaccurate and misleading.

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4 *MAC Directive: no evidence to support the safety concerns*, MEMO European Commission, 7 March 2014 - https://ec.europa.eu/commission/presscorner/detail/en/MEMO_14_168, and e.g. https://www.sae.org/standardsdev/tsb/cooperative/executivesummary.pdf

5 See SAE International CRP1234, *Industry Evaluation of low global warming potential refrigerant HFO1234yf*, 12/9/2008 - https://www.sae.org/standardsdev/tsb/cooperative/crp1234summary.pdf

HFO-1234yf was intentionally created to avoid negative environmental effects found in previous generation refrigerants (i.e. high GWP).

Substantial body of scientific data on health and environmental effects of HFO-1234yf and its main atmospheric decomposition products (incl. Trifluoroacetic acid (TFA)) is already available worldwide (e.g. studies of UN, OECD, EPA, REACH Registrations/Evaluation, individual scholars). All independent analysis demonstrates limited (*de minimis*) effects of HFO-1234yf emissions on humans and the environment for decades (e.g. UNEP, etc.) [6]. See in more details on recent studies and reports regarding HFO-1234yf and TFA in the ANNEX below.

2.2. Efficiency considerations (incl. for EV)

It is well established that R744 (CO_2) AC systems have reduced efficiency in hot climates leading to the increasing energy needs and thus to higher fuel and/or electricity consumption of a vehicle i.e. higher GHG emissions and consumer costs in comparison to HFO-1234yf systems.[7]

This problem elevates considerably in case of an EV, where additional power needs of the HVAC/TMS systems are not easily satisfied by an increase in fuel combustion and more frequent fuel stops. Increased energy needs result in reduced EV range – feeding a major consumer EV adoption concern.

In MAC applications, HFO-1234yf has a better life cycle climate performance than CO_2. Life Cycle Climate Performance (LCCP) Model[8] includes the CO_2 equivalence for refrigerant manufacturing, the direct emissions from vehicle refrigerant leaks and the total effect of HVAC system weight and AC compressor power on vehicle emissions. The SAE International study (referenced above) demonstrated that CO_2 HVAC systems resulted in a 10-15% increase in climate warming emissions when evaluated across population biased weather patterns for Europe and North America.[9]

The SAE International study was done based on vehicles with internal combustion engines and considered AC cooling only. For EVs, the thermal management system may also include a heat pump to improve energy efficiency for heating the vehicle. CO_2 does show some efficiency gains for heat pump operation but enhanced HFO-1234yf heat pump systems (HP) using all sources of waste heat approach the efficiency/effectiveness of CO_2 systems in cold conditions. Given increasing worldwide air temperatures and recognizing that most people in the EU are already exposed to hot conditions much more frequently than very cold ones (below -10°C or -20 °C) this gain is minimal.

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6 *E.g. Environmental effects of stratospheric ozone depletion, UV radiation, and interactions with climate change: UNEP Environmental Effects Assessment Panel*, Update 2020 - *https://link.springer.com/article/10.1007/s43630-020-00001-x, see also EFCTC summary publications at - https://www.fluorocarbons.org/news/explanation-tfa-is-different-to-most-other-pfas-learn-why/*

7 Section 4 in *Mobile air conditioning: The life-cycle costs and greenhouse-gas benefits of switching to alternative refrigerants and improving system efficiencies*, International Council on Clean Transportation, White paper, 2019 – https://theicct.org/publications/mobile-air-conditioning-cbe-20190308

8 Developed by 50 world experts from Industry, Governmental and Non-Governmental Organizations, National Laboratories, and Academia. Globally peer reviewed and accepted worldwide as the most credible method of comparing the Life Cycle GHG emissions of alternative refrigerants. See e.g. Papasavva, S., Hill, W. R., & Brown, R. O. (2008). *GREEN-MAC-LCCP: A tool for assessing life cycle greenhouse emissions of alternative refrigerants*. SAE Technical Series Paper 2008-01-0829. doi:10.4271/2008-01-0828, see also SAE standard - SAE J2766.

9 SAE International CRP1234, Industry Evaluation of low global warming potential refrigerant HFO1234yf, 12/9/2008 - https://www.sae.org/standardsdev/tsb/cooperative/crp1234summary.pdf

2.3. Socio-economic aspects of the HFO-1234yf use in MAC

HFO-1234yf MAC systems are well established and have been in use for nearly 10 years with more than 120 million vehicles on the road worldwide. All typical MAC components are reused with HFO-1234yf including compressors, condensers, evaporators, expansion valves, chillers, hoses and lines. HFO-1234yf (and the oils used) are compatible with all materials normally used in MAC/HVAC systems. Therefore, the transition from the high GWP refrigerant R-134a to HFO-1234yf has been relatively simple, fast and efficient because all existing components and designs of typical vehicle MAC systems worldwide may be used with the new refrigerant.

In contrast, CO_2 MAC/HVAC systems are expensive for consumers and automotive manufacturers alike. Virtually every current component in the AC system needs to be redesigned to accept the higher pressures and the trans-critical cycle necessary for MAC CO_2 refrigeration. Automotive HVAC suppliers will be required to recapitalize and retool their factories adding unnecessary economic costs to society. This will inevitably result in substantial higher mark-ups on all European cars, including the low and economy segments. These increases will directly affect EU citizens.

In addition, because of specific designs and higher prices, the EU automotive and supplier industry could lose global competitiveness as well, including in key export markets like North America and China.

2.4. EU Green Deal

Efficient and safe transportation in the EU is critical/vital for reaching objectives of the EU Green Deal. Currently EU road transport is responsible for ca. 20% of CO_2 emissions in EU (14% for cars & vans).[10] Taking into account the higher efficiency of HFO-1234yf in hot weather conditions (in comparison to CO_2), it is the best MAC refrigerant choice to reach EU climate change goals as well as to ensure ambitious decarbonisation targets set for 2030 (55% reductions of CO_2 emissions) and carbon neutrality by 2050.

According to estimates, potential HFO-1234yf substitution by CO_2 will increase CO_2 (equivalent) MAC related emissions by 10-15% for the 13 to 15 million vehicles sold each year and will increase vehicle costs. This will make the EU effort to decrease total CO_2 emissions harder and costlier and may impede overall EU decarbonisation targets.

2.5. Conclusions

Having a safe and efficient refrigerant with low health, safety and environmental effects are essential for MAC/HVAC and EV's TMS systems.

There are no other MAC refrigerants available today which provide as comprehensive a range of advantages as HFO-1234yf including low GWP, balanced energy efficiency, establishment in the market, negligible climate, health and environmental impacts, ease of service, safety in use and lower total cost of ownership. HFO-1234yf was intentionally developed to optimize these needs.

HFO-1234yf should not be compared to long chain PFAS compounds. It was specifically engineered to be an easy and effective substitute for R-134a and to break down in the atmosphere (creating its low GWP). The breakdown products have been widely studied and are considered to have an insignificant impact on the environment. In this respect, its main breakdown product TFA is universally recognized to not bioaccumulate.

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10 Transport & Environment (T&E) campaign group - https://www.transportenvironment.org/what-we-do/electric-cars/cars-co2

HFO-1234yf is an excellent refrigerant for MAC systems and is currently being used in several EV heat pump systems on the road today. Further EV development by automotive manufacturers brings many challenges on its own. Redesigning, reinventing, validating and commercializing of new refrigerants distracts and uses important resources that manufacturers need for their primary goals - the rapid development and commercialization of EVs in the EU and beyond. Encouraging EV development and their wide acceptance by all customers are two of the key elements needed to reach the objectives of the EU Green Deal.

END

ANNEX

- **Environmental fate of HFO-1234yf**

HFO-1234yf decomposes in the atmosphere in 5-15 days. The atmospheric degradation of HFO-1234yf leads to trifluoro acetyl fluoride (CF3C(O)F) which rapidly hydrolyzes to yield trifluoroacetic acid (TFA, CF3-C(O)OH).[11] A conversion rate of HFO-1234yf to TFA is almost 1:1 on a molar and w/v basis, ~100% molar yield. Amounts of other degradation products like 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). A large fraction of the formed TFA is deposited into the oceans.

There are a number of anthropogenic and natural sources of TFA and TFA salts in the environment. For instance, TFA a degradation product of several of the HCFCs, HFCs and HFOs, with the yield dependent on the identity of the compound. TFA is also widely used in the chemical industry with the amounts being released to the environment highly uncertain. Perfluorinated compounds and pharmaceutical products also contribute to TFA concentrations in the environment.

- **Health and environmental effects of TFA**

Substantial body of scientific data on health and environmental effects of HFO-1234yf and its main atmospheric decomposition product – TFA is already available worldwide (e.g. various studies of UN, OECD, EPA, REACH Registrations/Evaluation, individual scholars). All independent analysis demonstrates limited (*de minimis*) effects of HFO-1234yf emissions and resulted TFA on humans and the environment (e.g. UNEP, etc.).[12]

For example, the most recent report by the United Nations Environmental Program Environmental Effects Assessment Panel concluded that *"The current low concentration of trifluoroacetic acid (TFA) produced*

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11 E.g. Liji M. David, Mary Barth, Lena Höglund-Isaksson , Pallav Purohit , Guus J. M. Velders, Sam Glaser, and Akkihebbal. R. Ravishankara, *Trifluoroacetic acid deposition from emissions of HFO-1234yf in India, China, and the Middle East*, EGU, Atmospheric Chemistry and Physics Discussion - https://doi.org/10.5194/acp-2021-222

12 E.g. *Environmental effects of stratospheric ozone depletion, UV radiation, and interactions with climate change: UNEP Environmental Effects Assessment Panel*, Update 2020 - https://link.springer.com/article/10.1007/s43630-020-00001-x , see also detailed EFCTC summaries at - https://www.fluorocarbons.org/environment/environmental-impact/tfa-as-an-atmospheric-breakdown-product/

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."[13]

- **Recent Report of the German Environment Agency (UBA)**

In 2021, in preparations for the REACH restriction procedures for PFAS the German Environment Agency (UBA) initiated a number of publications/reports providing selective analysis of scientific data and risks assessments of TFA as the main degradation product of projected HFC/HFO refrigerants emissions.

The latest UBA Report on degradation products of halogenated refrigerants (i.e. TFA from HFO-1234yf emissions)[14] deserves particular attention due to the following major issues:

1) The main TFA health risks – i.e. drinking water contamination - are largely exaggerated.

In this respect, the UBA Report confirmed that the authorities possess enough scientific data to be able to set a toxicologically justified LW_{TW} for drinking water. The current national German LW_{TW} of 60 µg/L is based on the life-long tolerable daily intake of TFA via the drinking water (assumption: 2 L per day), in which no harm to human health is to be expected. In addition, the UBA set a target value of 10 pg/l.[15]

Further, the UBA Report details the recent rainfall study which aimed to quantify the current annual wet deposition of TFA in Germany. The study reported the precipitation-weighted average TFA concentration of all analysed wet deposition samples of 0.335 pg/L in February 2018 - January 2019. It is generally in line with the data reported in other regions around the globe.[16] It is noteworthy that this is considerably less (i.e. more than 180 times less) than the above guidance value 60 µg/L and target value 10 pg/L for drinking water (30 times less). The UBA press release states that rainfall concentrations of trifluoroacetate have risen sharply since the 1990s. Measurements for Germany reported for 1995-1996 (also in Switzerland and China) were around 0.12 pg/l mean. [17]

In other words, the reported TFA concentrations in wet deposition are 30-180 times lower than any established no effect levels and even considering the reported trends in last 23 years (3-time increase in 1995-2018); the real concentrations could not reach the German target dietary intake value for many decades. This is even assuming that HFC/HFO is a major source of TFA in rainfalls, although certain studies suggest that only less than 40% of TFA deposition can be explained based on fluorinated refrigerants (HFO/HFC).

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13 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

14 See in particular, Final report - *Persistent degradation products of halogenated refrigerants and blowing agents in the environment: type, environmental concentrations, and fate with particular regard to new halogenated substitutes with low global warming potential*, On behalf of the German Environment Agency, Project No. (FKZ) 3717 41 305 0, Report No. FB000452/ENG, 73/2021, May 2021 - https://www.umweltbundesamt.de/publikationen/persistent-degradation-products-of-halogenated

15 See e.g. at https://www.fluorocarbons.org/news/in-brief-tfa-drinking-water-guidance-value-in-germany/

16 Liji M. David, Mary Barth, Lena Höglund-Isaksson , Pallav Purohit , Guus J. M. Velders, Sam Glaser, and Akkihebbal. R. Ravishankara, *Trifluoroacetic acid deposition from emissions of HFO-1234yf in India, China, and the Middle East*, EGU, Atmospheric Chemistry and Physics Discussion - https://doi.org/10.5194/acp-2021-222

17 *Trifluoroacetic acid from fluorinated refrigerants contaminates rainwater,* Umweltbundesamt - https://www.umweltbundesamt.de/en/press/pressinformation/trifluoroacetic-acid-from-fluorinated-refrigerants

It is also important to highlight that although the comprehensive UNEP and WMO studies referred above also 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 health. However, UBA Report ignores these studies in the context of the effects of HFO/1234yf emissions.

2) The UBA Report significantly overestimates levels of projected HFO-1234yf emissions.

All refrigerants are used in closed systems (MAC, HVAC etc.) and could be recovered at the end-live stage of the system. Thus, refrigerants emissions are only possible due to unintended leaks during use and/or recovery operations.

However, the UBA Report acknowledges that in a scenario of maximum future use and emissions of halogenated substitutes technical developments or measures that could improve the tightness of the systems or measures to increase the recovery rates were not taken into account under this maximum scenario. This approach is misleading as continued improvements in technology, reliability servicing and maintenance have been evident throughout the historical refrigerant transitions. The model used to project emissions in the UBA Report has been already strongly criticized in the context of the F-gas review.[18]

In particular, for MAC, which is the main use of HFO-1234yf, the model assumes from 2010 to 2050 that there are no changes to the emission rate during the vehicle lifetime or the emission rate in case of destruction of the vehicle. The UBA Report assumes an emission rate of 10%/year during the whole service life. The emission rate in case of destruction of the vehicle is 70% for passenger cars. These estimates are very high and already differ from the reality.

It appears that the UBA report also underestimates the transition to electric vehicles by 2050. Forecasts suggest that by 2040 all new car sales globally could be electric.[19] Therefore, by 2050 as older vehicles are scrapped, the EU vehicle fleet will be virtually all electric. Electric vehicle air-conditioning and heat pump systems will, as a minimum, have electric compressors without shaft seals, rather than mechanically driven compressors. For conventional cars, the compressor shaft seal is responsible for about 50% of the refrigerant leakage rate for new vehicles and is a source of increased leakage in older vehicles. Therefore, electrically driven compressors, as they do not have a shaft seal, will result in decreased emission rates for new vehicles, and throughout the vehicle lifetime as there is no associated aging factor due to the absence of the shaft seal. Other technological changes may further reduce refrigerants emissions.

End of life recovery depends to some extent on the remaining refrigerant charge, which in turn is highly influenced by the leakage rate, and therefore the presence or absence of a compressor shaft seal. The requirements of the circular economy in the EU Green Deal will priorities reducing and reusing materials before recycling them. In the context of refrigerants, HFO-1234yf can be effectively recovered and reused following cleaning processes.

Forecasting emissions of HFO-1234yf through to 2050 based on 2010 technologies in the UBA Report resulted in assumptions that, for 2050, HFO-1234yf demand (51.2 kilotonnes) would be only slightly higher than the assumed emissions (47.7 kilotonnes). These unrealistic figures. The assumed emissions of the UBA Report are about 2-3 times higher than previous well-documented estimates in the literature

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18 See for example https://www.coolingpost.com/world-news/industry-groups-slam-f-gas-study/

19 *Why electric cars will take over sooner than you think*, BBC News, 1 June 2021, https://protect-eu.mimecast.com/s/YlgYCgLY3Fp4PzQuZhGg9?domain=bbc.co.uk

for the European region, US and Asia.[20] Moreover, the assumed demand and emissions levels in the UBA Report imply a rate of refrigerant recycling lower than 7% (emissions greater than 93%), which is not the reality already now.

In other words, the UBA Report assumed very high emission rates as well as ignored effects of any other emission mitigation measures such as proper disposal, recycling, and capturing at the end of a vehicle life. This had direct impact on assessments of TFA concentrations in rainwater and deposition in the environment and lead to incorrect conclusions regarding potential TFA risks.

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[20] Liji M. David, Mary Barth, Lena Höglund-Isaksson , Pallav Purohit , Guus J. M. Velders, Sam Glaser, and Akkihebbal. R. Ravishankara, Trifluoroacetic acid deposition from emissions of HFO-1234yf in India, China, and the Middle East, EGU, Atmospheric Chemistry and Physics Discussion - https://doi.org/10.5194/acp-2021-222

Honeywell

Aclar Manufacturing Survey Response , FINAL 13 October[1]

Previous submissions: Main; Extra

V. Questions - Section B - PFAS production (manufacturing) Questions in relation to the use

B1a) Do you have information that indicates that the information provided on the tonnage should be adjusted? NO
B1b) We do not manufacturer in the EU

B2a) Do you have information that indicates that the information provided on the emissions should be adjusted? NO
B2b) We do not manufacturer in the EU

B3) Please indicate if you have information on specific emission values (SPERCs) * for (groups of) PFAS, based on measurements and / or model calculations. NO

B4a) Do you have information that indicates that the information provided on the expected trend should be adjusted? YES

B4b) Market trend data is widely available by the specialized agencies (see below). As already shared, Honeywell estimates a 6.45% CAGR for PCTFE. Growth drivers for PCTFE use include new applications in bottles, vials, and bags driven by new biologic therapies. PCTFE plays a critical role in these packaging applications including moisture barrier properties and cryo-compatibility - https://www.mordorintelligence.com/industry-reports/europe-blister-packaging-market

Other reports:

EvaluatePharma – https://www.evaluate.com/thoughtleadership/pharma/evaluatepharma-world-preview-2020-outlook-2026

Mordor Intelligence - https://www.mordorintelligence.com/industryreports/pharmaceutical-plastic-bottles-market

Mordor Intelligence - https://www.researchandmarkets.com/reports/4330281/pharmaceutical-packaging-market-size-share-and#src-pos-1

https://www.transparencymarketresearch.com/pressrelease/uspharmaceutical-plastics-bottles-market.htm Coherent Market Insights - https://www.coherentmarketinsights.com/press-release/europepharmaceutical-drugs-market-2860
Summary report for review:*https://www.reach-clp-biozid-helpdesk.de/media/Helpdesk/download/Report%20summary%20production%20july%202021.pdf 1*
Summary report for review:*https://www.reach-clp-biozid-helpdesk.de/media/Helpdesk/download/Report%20summary%20production%20july%202021.pdf*

B5a) Do you have information on risk management measures to minimize the use, human exposure and emissions to the environment for your application of PFAS?
B4b) Please specify and/or refer to literature/public sources.
B4b)

Fluoropolymers applications in pharmaceutical packaging are subject to numerous strict RMM in the EU and worldwide, incl. production, use and waste stages. Being components of the primary packaging of pharmaceuticals, they are subject to in-depth assessments by the European Medical Agency (EMA) and national medicines authorities prior to marketing authorization of each drug. Their safety for humans, animals, and environment, including waste, is vigorously scrutinized/approved by EMA/national experts. They must also comply with the WHO and *EU Guideline on Plastic Immediate Packaging Materials* as well as with Directive 2002/72/EC and Regulation (EU) 10/2011 on plastic foods contact materials and *European Pharmacopoeia Monographs*. In addition, pharmaceutical packaging is subject to comprehensive RMM under the EU Directive 94/62/EC on packaging and packaging waste and Waste Framework Directive (Directive 2008/98/EC) that stipulate requirements on safety and eco-design (waste minimization) of packaging materials and their environmentally friendly waste treatment (collection, disposal, recycling, etc.). European Commission can further clarify and enhance respective RMM.

Questions - Section C - PFAS production (manufacturing) Questions in relation to alternatives (mainly for individual companies)
C1a) Do you have the possibility to produce fluorinated polymers without fluorinated processing aids? Yes
C1b) While we do not manufacturer in the EU, we can confirm no FPA are used in our manufacturer of PCTFE in any of our plants globally

V. Questions - Section D - PFAS production (manufacturing) Questions in relation to impact of legislative measures
D1) What is the economic impact (in euro) and social impact (e.g. jobs) on your business/company if the use of PFAS is prohibited:

Previous answer for awareness: Economic Impact: Thousands of drug regulatory registrations and dossiers specify Aclar film. Costly and time-consuming retesting and reregistration would need to be completed for all current drugs approved with Aclar packaging were PCTFE to be banned. There is no direct replacement for PCTFE film. Some drugs may require moisture barrier properties that can only be achieved by switching to an opaque cold form foil, resulting in larger pack sizes with reduced compliance and patient safety implications, as well as being in conflict with the EU resource efficiency targets. Social impact: job losses in EU for Honeywell 100 direct, 155 indirect and 375 in supply chain

D1a)
In three years
Exact economic and social impacts of PCTFE restrictions in the medicine sector are difficult to underestimate. An immediate discontinuation of PCTFE film use is not viable, as new packaging formats would need to be identified and qualified at a significant cost to pharmaceutical companies and this would take time to get to market.
Uses of PCTFE materials are specified in thousands of marketing authorizations, regulatory registrations and dossiers of thousands of pharmaceutical products (drugs, vaccines, medical devices, medicinal products, etc.), therefore we expect:

- Shortly after the restriction, shortages of many critical pharmaceuticals are highly possible.

- This prohibition will require very costly (ca. 100.0000 – 500.000 Euro) and time-consuming retesting and re-registration (5-10 years) would need to be completed for all current drugs approved with PCTFE (Aclar) packaging.Since there is no direct chemical and/or functional replacement for PCTFE films. Some drugs may require moisture barrier properties that can only be achieved by switching to an opaque cold form foil. This will result in (ca. 55%) larger pack sizes with increased compliance
  (dosage/timing) and patient safety risks, as well as conflicting with the EU resource efficiency and eco-packaging (minimal waste) objectives.

Expected job losses in EU for Honeywell (as already shared): 100 direct, 155 indirect and 375 in supply chain. This would be multiplied to cover others in the wider sector suppl chain

D1b) In ten year
Honeywell does not possess all required information and capacities to perform the necessary assessments over this time frame. We would assume it is the continuation and deepening of the above
D1c) Please explain by providing your calculations See above

D2) What is the economic impact (euro) on your business/company, if the following measures will become mandatory? Please make your (indicative) calculations transparent.
D2a) A maximum concentration of e.g. 0.1% (or less) PFAS is set in mixtures and/or articles.
Taking into account that under REACH, Aclar film is either a 100% pure PFAS substance, or an article with 100% PCTFE concentration, all Aclar imports into the EU would be prohibited.

Db) Obligation to label your products visibly with "Contains PFAS"

Unclear if this only refers to packaging which is end use facing. We as Honeywell are several steps away from this as a B2B supplier to other B2B actors in the chain. We supply our B2B customer with all data on products including PSS etc. More broadly be aware that packaging and labeling (text, size etc.) of pharmaceutical products are specified in conditions of marketing authorizations approved by EMA and/or national medicines authorities for each drug. Changes to the labeling (variations) must be notified to EMA/national authorities 90 days in advance. Therefore all (thousands) of pharmaceuticals in the EU/EEA with PCTFE (Aclar) packaging will have to pass the above
burdensome notification procedure to fulfil new labeling obligations.

D2c) Obligation to report amount of PFAS in use and respective emissions. N/A as we do not manufacture in the EU

D2d) Specific waste management requirements with the obligation to collect, treat or recycle PFAS containing waste separately.
Honeywell believes that this RMM (targeting end-of-life risks) is a more appropriate risk mitigation option for the pharmaceutical sector than blatant prohibitions on PCTFE use in pharma packaging. Coupled with voluntary production initiatives of EU PCTFE producers, these RMM could be the most effective risk mitigation as well as economically, technologically and societally neutral measures in practice. Although Honeywell is not a producer of pharmaceutical packaging as such, the company already provides customers (producers/processors of primary drug packaging) with required information on traceability and safe use of Aclar, incl. at waste stage.

To note: PCTFE fluoropolymers are not mobile in the environment, have negligible solubility and no systemic toxicity. There is no leaching of PFAS or hazardous substances throughout all life cycle of PCTFE packaging, including at disposal stage. There is sufficient evidence to conclude that PTFE/PCTFE are safe for normal municipal incineration and land field waste treatment. WHO Guidelines on packaging for pharmaceutical products also recommend both above techniques as appropriate waste treatment measures.

D2e) In case you are using PFAS polymers: no PFAS processing aids are allowed during polymer production.
While we do not manufacturer in the EU, we can confirm no FPA are used in our manufacturer of PCTFE in any of our plants globally

V. Questions - Section E - PFAS production (manufacturing) Specific questions for the use

E1) If available, please provide data on the amount of fluorinated additives used in fluoropolymer production (kg/ton). We do not manufacturer in the EU.

E2) If available, please provide data on the tonnages used (yearly EEA) and applications of PTFE and PVDF micropowders.
While we do not manufacturer in the EU, we can confirm no such micropowders are used in our manufacturer of PCTFE in any of our plants globally

E3) If available, please provide information on the production of PFAS alternatives N/A

Previous messaging for awareness

We do not agree that PCTFE should be characerized or regulated as a PFAS as it is non-toxic. Attempting to regulate all such substances as one group, based only on structural characteristics and ongoing risk assessment studies for compounds that represent <1% of such substances, is not scientifically justified nor appropriate to guide effective regulation. Such an attempt ignores the chemically diverse behaviour found among similarly structured substances.

It is well known that PCTFE is inert and not bio accumulative. PCTFE does not interact with the environment or human or animal organisms. It is approved for use in medical devices and parenteral applications as a certified US Pharmacopeia Class VI material. It is inappropriate to regulate PCTFE based only on its structural similarity with other compounds, neglecting its bioinertness, unique characteristics and societal benefits.

Furthermore, PCTFE is indispensable in the delivery and preservation of safe pharmaceuticals that benefit a broad range of markets including originator and generic pharmaceuticals, over-the-counter (OTC), pharmaceutical and animal health packaging. Aclar is used in thousands of oral solid therapies across all therapeutic areas including nervous system, cardiovascular, metabolic, hormonal, antipsychotic, and oncology.

There isn't a good alternative to PCTFE film for packaging use. The below four characteristics differentiate Aclar film from other packaging alternatives.

Honeywell

1. Aclar film provides the highest moisture barrier when compared to other thermoformable polymers, Aclar film is crystal clear and colorless. The only alternative to Aclar that is capable of achieving the same moisture barrier is cold form foil (Aluminum laminated with polymers), which requires larger pack sizes and is opaque.

2. In applications where dosage, timing, and potential abuse are critical, patients must be able to use colorless transparent packaging formats to ensure compliance and patient safety. Ultra-high moisture barrier in colorless transparent packaging is important to patient safety and compliance.

3. In addition, pack size can be reduced by up to 55% (volume) with Aclar when compared to the same product packed with cold form foil contributing to the EU's resource efficiency goals: creating a smaller pack size with Aclar directly reduces raw material (film or foil) usage, scrap production, warehousing expense and transportation costs.

4. Because Aclar does not require the use of additives such as plasticizers that may migrate into drug products, it can help to ensure drug product safety, efficacy, and quality

END

Honeywell

Aclar Medical devices survey
FINAL, 13 October 2021

Report summary medical devices july 2021.pdf

Previous submission: Packaging

V. Questions - Section B - Medical devices Questions in relation to the use (mainly for industry associations)

Includes tonnage for medical devices **incl. packaging (mainly polymers)**

B1a) Do you have information that indicates that the information provided on the tonnage should be adjusted? NO
B1b) Honeywell does not manufacture PCTFE (Aclar) fluoropolymers in the EU/EEA.
According to own estimates, our total average annual imported volumes of PCTFE fluoropolymers used in medicinal/pharmaceutical packaging in the EU in 2015-2020 was ca. 89 tonnes. Here. In comparison with total volumes of fluoropolymers used in the EU (ca. 65 000 tonnes in 2018), tonnages of PCTFE and Aclar uses in pharmaceutical/medicinal packaging applications in the EU are negligible – 0,001-0,002%.

B2a) Do you have information that indicates that the information provided on the emissions should be adjusted? YES
B2b)

- Production: Aclar production takes place outside the EU/EEA, i.e. 0% EU emissions during production of Aclar materials.
- Processing: PCTFE (Aclar) films are further processed into blister packaging by specialized processors in the EU. Although, exact data is not disclosed to Honeywell, it is estimated that corresponding processing emissions are nearly at 2% or very low as previously shared and in line with industry standards.
- Use: Fluoropolymers, including PCTFE, in pharmaceutical packaging must have very low (0%) emission/leaching profile during use (subject to EMA/national specifications (*European Pharmacopeia*) and approval).
- Waste: Most pharmaceutical packaging waste in the EU is incinerated (statutory recommended)

B3) Please indicate if you have information on specific emission values (SPERCs) * for (groups of)
PFAS, based on measurements and / or model calculations. NO

B4a) Do you have information that indicates that the information provided on the expected trend should be adjusted? YES
B4b) Market trend data is widely available by the specialized agencies (see below). As already shared, Honeywell estimates a 6.45% CAGR for PCTFE. Growth drivers for PCTFE use include new applications in bottles, vials, and bags driven by new biologic therapies. PCTFE plays a critical role in these packaging applications including moisture barrier properties and cryo-compatibility -
https://www.mordorintelligence.com/industry-reports/europe-blister-packaging-market
Other reports:
EvaluatePharma – https://www.evaluate.com/thoughtleadership/pharma/evaluatepharma-world-preview-2020-outlook-2026
Mordor Intelligence - https://www.mordorintelligence.com/industryreports/pharmaceutical-plastic-bottles-market

Mordor Intelligence - https://www.researchandmarkets.com/reports/4330281/pharmaceutical-packaging-market-size-share-and#src-pos-1
https://www.transparencymarketresearch.com/pressrelease/uspharmaceutical-plastics-bottles-market.htm

Honeywell

Coherent Market Insights - https://www.coherentmarketinsights.com/press-release/europepharmaceutical-drugs-market-2860

B5a) Do you have information on risk management measures to minimize the use, human exposure and emissions to the environment for your application of PFAS? YES
B4b)
Fluoropolymers applications in pharmaceutical packaging are subject to numerous strict RMM in the EU and worldwide, incl. production, use and waste stages. Being components of the primary packaging of pharmaceuticals, they are subject to in-depth assessments by the European Medical Agency (EMA) and national medicines authorities prior to marketing authorization of each drug. Their safety for humans, animals and environment, including waste, are vigorously scrutinized/approved by EMA/national experts. They must also comply with the WHO and *EU Guideline on Plastic Immediate Packaging Materials* as well as with Directive 2002/72/EC and Regulation (EU) 10/2011 on plastic foods contact materials and *European Pharmacopoeia Monographs*. In addition, pharmaceutical packaging is subject to comprehensive RMM under the EU Directive 94/62/EC on packaging and packaging waste and Waste Framework Directive (Directive 2008/98/EC) that stipulate requirements on safety and eco-design (waste minimization) of packaging materials and their environmentally friendly waste treatment (collection, disposal, recycling, etc.). European Commission can further clarify and enhance respective RMM.

V. Questions - Section C - Medical devices Questions in relation to alternatives

C1) What is the specific application/functionality of PFAS in your product(s)/processes? Aclar film provides the highest moisture barrier compared to other thermoformable polymers, including polyethylene terephthalate (PET) & ethylene vinyl alcohol (EVOH). It is crystal clear and colorless. The only alternative capable of achieving the same moisture barrier is cold form foil, which requires larger pack sizes and is opaque.
In applications where dosage, timing, and potential abuse are critical, drug companies must be able to use colorless transparent packaging formats to ensure compliance and patient safety. Ultrahigh moisture barrier in colorless transparent packaging is important to patient safety and compliance. In addition, Aclar pack size can

be reduced by up to 55% (volume) compared to the same product packed with cold form foil contributing to the EU's resource efficiency goals: creating a smaller pack size with Aclar directly reduces raw material (film/foil) usage, scrap production, warehousing expenses and transportation costs. Because Aclar does not require the use of additives such as polymerization aids, processing aids or plasticizers that could migrate into drug products, it can help to ensure drug product safety, efficacy, and quality.

C2a) Are in your view the listed non-PFAS alternatives technically feasible in your product(s)/processes? NO
C2b) There is no list shared. Aclar film's unique properties mean it is non-viable to substitute PCTFE with an alternative chemical or technique that maintains all critical properties and marketing authorization conditions/specifications approved for each drug. There is no direct replacement for PCTFE film in case of its immediate discontinuation of supply. Certain critical drugs may require moisture barrier properties that can only be achieved by switching to an opaque cold form foil, resulting in larger pack sizes with increasing patient safety and compliance risks/ implications, as well as conflicting with the EU resource efficiency targets and eco-design packaging (waste minimization) principles.

C3a) Are in your view the listed non-PFAS alternatives economically feasible in your product(s)/processes? NO

C3b) There is no list shared. PCTFE film non-use is not viable, as new packaging materials and formats would need to be identified and approved by EMA/national authorities at a significant cost to pharmaceutical companies and high administrative burden to the authorities. Thousands of drug marketing authorizations and regulatory Dossiers specify Aclar films as an approved packaging material.
Costly and time-consuming retesting (including for key *"stability characteristics"* of drugs) and reregistration would need to be completed for all current drugs approved by EMA/national authorities with Aclar packaging.

C4a) Do you have information on the alternatives' risk profile? NO
C4b) Please describe

There is potential for higher risk of exposure to hazardous substances in alternatives used to meet the high standards of PCTFE fluoropolymers in many applications. Cold form foil, which can achieve the same moisture barrier, is not transparent and thus increase risks of the patient compliance with prescriptions and safety, will result in increased packaging size by 55% in comparison with PCTFE (Aclar). Also worth considering cold form foil generally contains a layer of PVC in addition to the aluminum, this extra layer may discharge hydrochloric acid and dioxins during incineration and thus is harmful to the environment.

These alternatives bring higher safety risks, increases in emissions resulting from technical regression, and could put the EU goals for climate and energy at risk. Aclar may further be laminated to materials such as polyester and polypropylene.

C5a) Are there legal approval schemes for your product(s)/processes, which have to be taken into account in case PFAS alternatives will be used YES

C5b)Please specify and/or refer to literature/public sources
Primary packaging of any pharmaceutical product directly affects one of its key properties - *"stability characteristics"*. The latter refer to the extent to which an active substance or a final drug preserves its quality, safety, and efficacy throughout its period of storage and use. Stability characteristics is an integral part of the marketing authorization conditions/Dossier specified by the EMA/national medicines authorities for each pharmaceutical. Changes in these specifications require additional testing (100.000 – 500.000 Euro) and approval (26.000 – 86.000 Euro) by the authorities for each drug.
In cases where alternative packaging would not provide satisfactory stability characteristics of active substances or final medicinal products, necessary changes will be required for medicinal formulations as such. Afterwards, the new drugs must be approved by EMA/national authorities.

C5c) What is the average approval time? Pharmaceutical products (both for human and animal uses) require approval (prior marketing authorization) by the EMA and/or national competent regulatory authorities. Any change (variation) in the primary packaging of a pharmaceutical product or in its formulation would require R&D work, testing, preparation and submission of new data to the regulatory agency and approval timelines. This work may range from 5-10 years depending on the actual pharmaceutical product and company resources.

Honeywell

Our overarching concern is that because of the above serious drug shortages will happen once this possible PFAS REACH restriction is introduced and PCTFE can no longer be used. There will be an interruption of supply to potentially thousands of medicines registered in PCTFE packaging affecting the lives of patients across the EU.

C6a) Do you actively work on finding alternatives? NO

C6b) Please specify

According to our knowledge, there are no acceptable chemical or functional substitutes to PCTFE films available in the market. Other materials do not provide required properties/benefits and characteristics specified in respective marketing authorizations.

C6c) If alternatives have been identified as potentially suitable, which timescale do you foresee for a complete transition to those? Please explain N/A

C6d) Do you have information on additional alternatives for any of the described applications that have not been disclosed in the attached information? N/A

V. Questions - Section D - Medical devices Questions in relation to impact of legislative measures

D1) What is the economic impact (in euro) and social impact (e.g. jobs) on your business/company if the use of PFAS is prohibited:

D1a) In three years

Exact economic and social impacts of PCTFE restrictions in medicine sector are difficult to underestimate. Uses of PCTFE materials are specified in thousands of marketing authorizations, regulatory registrations and dossiers of thousands of pharmaceutical products (drugs, vaccines, medical devices, medicinal products, etc.), therefore we expect:

- Shortly after the restriction, shortages of many critical pharmaceuticals are highly possible.
- This prohibition will require very costly (ca. 100.0000 – 500.000 Euro) and time-consuming re-testing and re-registration (5-10 years) would need to be completed for all current drugs approved with PCTFE (Aclar) packaging.
- Since there is no direct chemical and/or functional replacement for PCTFE films. Some drugs may require moisture barrier properties that can only be achieved by switching to an opaque cold form foil. This will result in (ca. 55%) larger pack sizes with increased compliance (dosage/timing) and patient safety risks, as well as being in conflict with the EU resource efficiency and eco-packaging (minimal waste) objectives.
- Expected job losses in EU for Honeywell (as already shared): 100 direct, 155 indirect and 375 in supply chain. This would be multiplied to cover others in the wider sector suppl chain. D1b) In ten years- Honeywell does not possess all required information and capacities to perform the necessary assessments over this time frame. We would assume it is the continuation and deepening of the above

Honeywell

D1c) Please explain by providing your calculations See replies in section D1a) above.

D2) What is the economic impact (euro) on your business/company, if the following measures will become mandatory? Please make your (indicative) calculations transparent.
D2a) A maximum concentration of e.g. 0.1% (or less) PFAS is set in mixtures and/or articles.

Taking into account that under its REACH registration, Aclar film is either a 100% pure PFAS substance, or an article with 100% PCTFE concentration, all Aclar imports into the EU will be prohibited.

D2b) Obligation to label your products visibly with "Contains PFAS"
Unclear if this only refers to packaging which is end use facing. We as Honeywell are several steps away from this as a B2B supplier to other B2B actors in the chain. We supply our B2B customer with all data on products including, PSS etc. More broadly be aware that packaging and labeling (text, size etc.) of pharmaceutical products are specified in

conditions of marketing authorizations approved by EMA and/or national medicines authorities for each drug. Changes to the labeling (variations) must be notified to EMA/national authorities 90 days in advance. Therefore all (thousands) of pharmaceuticals in the EU/EEA with PCTFE (Aclar) packaging will have to pass the above burdensome notification procedure to fulfil new labeling obligations.

D2c) Obligation to report amount of PFAS in use and respective emissions.
N/A. Honeywell does not manufacture or process PCTFE (Aclar) materials in the EU.

D2d) Specific waste management requirements with the obligation to collect, treat or recycle PFAS containing waste separately.
Honeywell believes that this RMM (targeting end-of-life risks) is a more appropriate risk mitigation option for the pharmaceutical sector than blatant prohibitions on PCTFE use in pharma packaging. Coupled with voluntary production initiatives of EU PCTFE producers, these RMM could be the most effective risk mitigation as well as economically, technologically and societally neutral measures in practice. Although Honeywell is not a producer of pharmaceutical packaging as such, the company already provides customers (producers/processors of primary drug packaging) with required information on traceability and safe use of Aclar, incl. at waste stage.
To note: PCTFE fluoropolymers are not mobile in the environment, have negligible solubility and no systemic toxicity. There is no leaching of PFAS or hazardous substances throughout all life cycle of PCTFE packaging, including at disposal stage. There is sufficient evidence to conclude that PTFE/PCTFE are safe for normal municipal incineration and land field waste treatment. WHO Guidelines on packaging for pharmaceutical products also recommend both above technics as appropriate waste treatment measures.

D2e) In case you are using PFAS polymers: no PFAS processing aids are allowed during polymer production. While we do not manufacture in the EU, we can confirm no PFAS processing aids are used in our manufacturer of PCTFE in any of our plants globally. Our Aclar materials are produced without involving other PFAS at any stage in the process. PCTFE is manufactured by homopolymerization of its monomer, chlorotrifluoroethylene (CTFE, CF2=CFCl), which is not listed as PFAS in OECD or EPA inventories. It is also outside the scope of the updated OECD definition of PFAS substances. It is well established that PCTFE, if and when released to the environment, rapidly decomposes in less than 2 days, to produce non-PFAS products that have a negligible environmental impact.

V. Questions - Section E - Medical devices Specific questions for the use
E1)If available, please provide information on PFAS emissions during medical device production.

Not available. Honeywell produce PCTFE-based packaging materials (Aclar) outside the EU and supply them to the EU producers (processors) of composite primary pharmaceutical packaging as such. The company does not possess information on PFAS emissions during production of final pharmaceutical packaging products in the EU.
See B2b) above.
E2) If available, please provide information on market trends for contrast media, propellants, F-gases and/or medical devices.
see **Q&A B4a**
E3) If available, please provide information on fluorine-free alternatives for medical devices.
See replies in Section C above. ***END***

Honeywell

National Institute for Public Health and the Environment
Ministry of Health, Welfare and Sport

baua: Bundesanstalt für Arbeitsschutz und Arbeitsmedizin

KEMI Swedish Chemicals Agency

NORWEGIAN ENVIRONMENT AGENCY

Ministry of Environment and Food of Denmark
Environmental Protection Agency

Summary page:
2nd Stakeholder Consultation on a Restriction for PFAS

I. Reasons and aims of this analysis

Update: The submission period was extended from the 19th of September to the 17th of October 2021!

The competent authorities for REACH of the Netherlands, Germany, Denmark, Sweden and Norway are currently preparing a REACH Annex XV Restriction Dossier for the group of PFAS (per- and polyfluoroalkyl substances) described below (as defined under Section II. Substances) since all these substances are considered to be persistent.

The consequences of this persistence include that the presence of these substances in the environment is practically irreversible, and pose an unacceptable risk to the environment a nd humans. All uses of PFAS (professional and industrial uses, consumer uses of mixtures and articles) result in emissions into the environment and contribute to the overall concentrations of PFAS in the environment. Many members of this group already occur ubiquitously in the environment and contaminate the ground- and untreated water due to their high mobility. In addition, some of these substances accumulate in biota and/or are suspected to be toxic.

In view of these properties, the above mentioned competent authorities for REACH are considering proposing EU-wide measures covering all PFAS (as defined under Section II. Substances) to reduce those risks.

This questionnaire is intended to provide you/the respondents with the current overview the five authorities have on the different uses of PFAS. By checking the presented data and providing feedback you/the respondents can ensure that the correct information is used for the assessment and preparation of a REACH Annex XV Restriction Dossier. Furthermore, you/the respondents can provide the authorities with currently still lacking information. EEA tonnages & emissions presented depict the European perspective, which the authorities created from the gathered information. If tonnages or emissions are challenged, please do so at European level, not at individual company level. For alternatives (and transition costs) this is slightly different and individual companies likely have valuable information.

I. Reasons and aims of this analysis

General:

The purpose of the ‘investigation report summaries’ (download is possible on the next page) is to present our current knowledge and understanding regarding uses of PFAS with a focus on use tonnages, emissions, alternatives and substitution costs, etc. The data are important for both risk assessment and the socio economic analysis (SEA).

The investigation report summaries have been prepared based on more detailed PFAS use investigations. It should be noted that these investigation report summaries should not be considered to be equivalent to the Annex XV restriction report, which is in a preparation phase. Presented data reflect the current knowledge and during the project new data might become available. It is not guaranteed that the information presented here will be used in the Annex XV restriction report or in the presented way. For instance: Presented quantities or costs could be higher or lower.
The information provided is largely of a general nature and is not intended to address the specific circumstances of any particular individual or entity. Further, the information is not professional or legal advice. In case respondents fill out the survey several times, only the latest entry will be considered.

Scope:
This survey is intended to provide an opportunity for stakeholders to confirm the understanding of the five countries prepararing the restriction proposal, or provide updated information, on PFAS uses, including tonnages, emissions, alternatives and transition costs. Information can also be valuable, if it confirms estimates that are currently marked as uncertain by the five countries. This survey is not intended as an opportunity to provide feedback on the essential use concept. This survey is not intended as an opportunity to provide feedback on the (chemical) scope of the proposed restriction.
The use of PFAS in fire fighting foams is not part of this call for evidence. ECHA is preparing a separate Annex XV restriction dossier on this use.
Stakeholders are invited to add information on uses not mentioned in the report summaries under section A (general questions).

Public sources / literature references:
Presented numbers (i.a. tonnages & emissions) represent the situation in the European Economic Area (EEA). If you have a different view, please provide this information on EEA level with reference to public sources.
In case transition times are applicable due to substitution, please refer to the respective legal text where possible. In instances where the information presented in the investigation report summaries is challenged, but no reference to literature or public sources are made to justify such challenges, we are unlikely to be able to take the comments into account.

Others:
PFAS tonnages for the described uses cannot be added up for a full tonnage overview as this might lead to double counting. In case no information is available, the authorities will follow a reasonable worst-case approach when estimating emissions to the environment. Concerning the presented summaries, the authorities from the five countries do not accept any liability with regard to the use that may be made of the information contained. Use of the information in these summaries remains the sole responsibility of the reader. Although, the information provided in the summaries has been prepared with the utmost care, possible errors or omissions cannot be excluded. The authorities from the five countries do not accept any liability with regards to any such errors or omissions.

II. PFAS in scope

As indicated by the name, per- and polyfluoroalkyl substances (PFASs) comprise a group of organic substances containing alkyl groups on which all or many of the hydrogen atoms have been replaced with fluorine as structural fragments.

PFAS in the scope of this call for evidence have the following structural formula: X-(-CF_2-)n- X'

with n ≥ 1 and X, X' not being H (thus including X-CF_3) meaning fluorinated substances

that contain at least one aliphatic carbon atom that is both, saturated and fully fluorinated, i.e. any chemical with at least one perfluorinated methyl group ($-CF_3$) or at least one perfluorinated methylene group ($-CF_2-$), including branched fluoroalkyl groups and substances containing ether linkages, fluoropolymers and side chain fluorinated polymers.

Although all PFAS will be considered for regulation, a non-exhaustive list of the most frequently used substances and substance groups may be found in the supplementary document accompanying this questionnaire and consultation which can be downloaded under the following link: Supplementary document.pdf

III. Target group of this questionnaire

Questions are addressed to the whole supply chain including **industry associations, manufacturers, importers, distributors and downstream users**.

Of interest is information on **PFAS** and **alternatives to PFAS.** Both, PFAS as such and PFAS contained in mixtures and articles are of relevance. Alternatives include chemical (non-fluorinated) as well as technical replacements for PFAS.

Please note that this questionnaire consists of 66 pages in total. It will, however, allow you to navigate through blocks of questions depending on your type of information or data. Hence, you will be able to specifically respond to the questions relevant to you. There will be max. 4 pages of questions per use ticked in Section A (general questions).

In the table below, the hyperlinks on the right side will allow you to download summary reports for the different uses for which further information is requested. In some cases a second hyperlink is available. In these cases the lead authority assessing the use already published a summary report on their website.

Use	Hyperlinks to report summaries
Cleaning agents, polishes and waxes (non-industrial uses)	Report summary cleaning agents polishes waxes july 2021.pdf
Cosmetics	Report summary cosmetics july 2021.pdf
Food contact materials & packaging	Report summary food contact materials and packaging july 2021.pdf
Lubricants	Report summary lubricants july 2021.pdf
Construction products	Report summary construction july 2021.pdf
Medical devices	Report summary medical devices july 2021.pdf
Medicinal products	Report summary medicinal products july 2021.pdf
Metal plating & manufacturing of metal products	Report summary metal plating and manufacturing of metal products july 2021.pdf

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PFAS production (manufacturing)	Report summary PFAS and PFAS polymer production july 2021.pdf
Ski treatment	Report summary ski treatment july 2021.pdf PFAS in the treatment of skis - use, emissions and alternatives
TULAC (textiles, upholstery, leather, apparel and carpets)	Report summary TULAC july 2021.pdf
Petroleum & mining	Report summary petroleum and mining july 2021.pdf PFAS in mining and petroleum industry – use, emissions and alternatives
F-gas uses	Report summary F gas uses july 2021.pdf Application of Fluorinated Gases (F-Gases) in the European Economic Area
Electronics & energy	Report summary electronics and energy july 2021.pdf
Transportation	Report summary transportation july 2021.pdf
Waste	Report summary waste july 2021.pdf

IV. Information on institute/organisation/person & data protection rights

Information on institute/organisation/person & data protection rights can be downloaded via the following link: GDPR.pdf

Fields marked with * on this page are mandatory fields.

PERMISSION FOR INFORMATION PURPOSES: I agree to the personal data I provide in the present survey, including my name and my e-mail address, to be collected, processed and stored for potential follow-up questions regarding this survey by the service provider of the Federal Institute for Occupational Safety and Health (BAuA), namely Webropol Deutschland GmbH, and to these being subsequently stored in the database of the Federal Office for Chemicals.

*

Yes

Information on institute/organisation/person

Honeywell

Name	Mary
Surname	Walsh
Name of institute/organisation	Honeywell Europe
E-Mail	[redacted]@Honeywell.com

Can we contact you with follow-up questions? *

Yes

Note on Confidentiality of information and data

I understand that it is my responsibility not to include confidential information in responses to general comments and in any responses to requests for specific information (e.g. company name, properties, assets, costs etc.). The competent authorities for REACH will not be held liable for any damages caused.

*

Y e s

I understand that it is my responsibility to mark confidential data and attachments as confidential. *

Yes

V. Questions - Section A - General questions

For which use would you like to submit information? Please select all uses on which you would like to provide information.

PFAS production (manufacturing)
F-gases
Transportation

If relevant, please further specify your use (e.g. textiles used in personal protective equipment).

Honeywell produces and sells refrigerants, industrial solvents, blowing agents, used in manufacture of foam, and aerosol propellants. This covers traditional HFCs and HFCs and blends.

Are certain uses of PFAS missing in the categories above?

N/A

V. Questions - Section B - Cleaning agents, polishes & waxes (non-industrial uses)

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Questions in relation to the use (mainly for industry associations)

The following linked information presents the current picture: Report summary cleaning agents polishes waxes july 2021.pdf

In the tables presented on this page and the following, '?' in the cells show that the authorities do not have any information available. Input to fill these gaps is highly appreciated.

Sub-Use	Tonnage (tonnes/PFAS) per year in the EEA	Expected trend (--/-/0/+/++)[1]	Emissions/year in EEA[2] (tonnes/PFAS)
Cleaners (for glass, metal, ceramic, carpet and upholstery)	?	?	?
Aftermarket carpet care	?	?	?
Dishwashing products (rinse aids)	?	?	?
Dry cleaning products	?	?	?
Waxes and polishes (for i.e. furniture, floors and cars)	?	?	?
Windshield wiper fluids	?	?	?
Windshield treatments (for automobiles)	?	?	?
Rain-repellent fluids	?	?	?

[1] -- = strong decrease, - = decrease, + = increase, ++ = strong increase, 0 = neutral

[2] Emissions relate to mixture/article production and mixture/article use. They do not include PFAS production and the waste stage of the articles. These emissions are covered in a separate section.

V. Questions - Section C - Cleaning agents, polishes & waxes (non-industrial uses)

Questions in relation to alternatives (mainly for individual companies)

Sub-Use	Non-PFAS alternatives
Cleaners (for glass, metal, ceramic, carpet and upholstery)	- hydrocarbon or silicone based surfactants - siloxane gemini surfactants
Aftermarket carpet care	- silicone dioxide
Dishwashing products (rinse aids)	?
Dry cleaning products	?
Waxes and polishes (for i.e. furniture, floors and cars)	- carnauba wax - nonfluorinated non-ionic or anionic surfactants

Windshield wiper fluids	- non fluorinated surfactants (e.g. sodium dioctyl sulfosuccinate)
Windshield treatments (for automobiles)	- polydimethylsiloxane
Rain-repellent fluids	?

V. Questions - Section D - Cleaning agents, polishes & waxes (non-industrial uses)

Questions in relation to impact of legislative measures (for companies and industry associations)

V. Questions - Section B - Cosmetics

Questions in relation to the use (mainly for industry associations)

The following linked information presents the current picture: Report summary cosmetics july 2021.pdf

In the tables presented on this page and the following, '?' in the cells show that the authorities do not have any information available. Input to fill these gaps is highly appreciated.

Sub-Use	Tonnage (tonnes F) per year in the EEA[1]	Expected trend (--/-/0/+/++)[2]	TF Emission[3]/year EEA (tonnes F)	EOF Emissions[4]/year in EEA[5] (tonnes F)
Skin Care	8.2	0	6.2	0.009
Toiletries	0.6	0	0.5	0.3
Hair Care	1	0	0.9	0.5
Perfumes and Fragrances	0	0	0	0
Decorative Cosmetics	1.2	0	0.7	0.2

[1] Based on the total fluorine (TF) measurements. Quantities PFAS/year are obtained by using a conversion factor of
1.4-2.0.

[2] -- = strong decrease, - = decrease, + = increase, ++ = strong increase, 0 = neutral

[3] Emissions to wastewater based on the total fluorine (TF) measurements.

[4] Emissions to wastewater based on total extractable organic fluorine (EOF) measurements.

[5] Emissions relate to mixture/article use. They do not include PFAS production and the waste stage of the articles. These emissions are covered in a separate section. Also note that emissions do not include mixture/article production..

V. Questions - Section C - Cosmetics

Questions in relation to alternatives (mainly for individual companies)

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Sub-Use	Non-PFAS alternatives[1]
Skin care	?
Toiletries	?
Hair Care	?
Perfumes and fragrances	?
Decorative cosmetics	?

[1] Based on the information gathered so far, the authorities conclude that PFAS can be replaced by other ingredients and do not have unique functions. One reason is that there are far more non-PFAS cosmetic products within the same product categories as the PFAS containing products.

V. Questions - Section D - Cosmetics
Questions in relation to impact of legislative measures (for companies and industry associations)
V. Questions - Section E - Cosmetics
Specific questions for the use
V. Questions - Section B - Food contact materials & packaging
Questions in relation to the use (mainly for industry associations)

The following linked information presents the current picture: Report summary food contact materials and packaging july 2021.pdf

In the tables presented on this page and the following, '?' in the cells show that the authorities do not have any information available. Input to fill these gaps is highly appreciated.

Sub-Use	Tonnage (tonnes/PFAS) per year in the EEA PFAS solely polymers in table	Expected trend (--/-/0/+/++)[1]	Emissions/year in EEA[2] (tonnes/PFAS)
Packaging	Product: 41,351,000 (paper and board) Product: 20,500,000 (plastic packaging) PFAS: 827 - 4,962 (in paper and board)	+ (3%)	124 - 871

	PFAS: ? (for plastic packaging)		
Cookware	Product: ? PFAS: 3,500 (Plastic Europe, AFW, 2017)	+ (5%)	1,633 - 4,716 (mainly recoating emissions)
Industrial applications	Product: ? PFAS: 3,000[3] (Plastic Europe, AFW, 2017)	++ (10 - 20%)	

[1] -- = strong decrease, - = decrease, + = increase, ++ = strong increase, 0 = neutral

[2] Emissions relate to mixture/article production and mixture/article use. They do not include PFAS production and the waste
stage of the articles. These emissions are covered in a separate section.

[3] Including pharmaceuticals (could not be disaggregated).

V. Questions - Section C - Food contact material & packaging Questions in relation to alternatives (mainly for individual companies)

Sub-Use	Non-PFAS alternatives
Packaging	- natural greaseproof paper - vegetable parchment - clay coatings - silicone - biopolymers (e.g. chitosan, starch, cellulose, polyvinyl alcohol, bioplastics such as polylactic acid (PLA), biowaxes) - synthesis plastics (e.g. low-density polyethylene (LDPE), linear low-density polyethylene (LLDPE), high density polyethylene (HDPE), polypropylene (PE), ethylene vinyl alcohol (EVOH), polyvinyl alcohol (PVOH), polyvinylidene chloride (PVDC), polyethylene terephthalate (PET)) - microfibrillar cellulose (MFC), cellulose nanofibrils (CNFs), cellulose nanocrystals (CNCs) - aqueous dispersions of co-polymers (e.g. styrene acrylic emulsion (SAE)) - aqueous dispersions of waxes (e.g. TopScreen) - water soluble hydroxyethylcellulose (HEC) - alkyl succinic anhydride (ASA), alkyl ketene dimer (AKD)

	- aluminium foil - lamination using impermeable barriers - other plant fibres (miscanthus, etc.) - bitumen coating - re-usable materials
Consumer cookware	- 'ceramic' coatings (sol-gel) as replacement of coating material - silicone coatings as replacement of coating material - silicone cookware (not coated metal) as alternative base material, uncoated - superhydrophobic coatings and hydrophobic coatings as replacement of coating material (Nanoscopic layer which is able to resist water. They are made from different materials like zinc oxide polystyrene, precipitated calcium carbonate, carbon nano-tube substances, manganese oxide polystyrene.) - enamelled cast iron / seasoned cast iron as alternative base material and non-stick coating - full ceramic cookware (not just coated) as alternative base material - carbon steel as alternative base material, uncoated - anodized aluminium coating as alternative base material, may be coated - stainless steel as alternative base material, uncoated - copper as alternative base material, uncoated
Industrial applications	- stainless steel - ceramic coatings - silicone and silicone coatings - synthetic rubbers and similar compounds (nitrile rubber, ethylene propylene rubber, neoprene, PES (polyethersulfone))

V. Questions - Section D - Food contact material & packaging

Questions in relation to impact of legislative measures (for companies and industry associations)

V. Questions - Section B - Lubricants

Questions in relation to the use (mainly for industry associations)

The following linked information presents the current picture: Report summary lubricants july 2021.pdf

In the tables presented on this page and the following, '?' in the cells show that the authorities do not have any information available. Input to fill these gaps is highly appreciated.

Sub-Use	Tonnage (tonnes/PFAS) per year in the EEA	Expected trend (--/-/0/+/++)[1]	Emissions/year in EEA[2] (tonnes/PFAS)
Formulation of lubricants	< 3,000	+ (5% up to 2030)	in soil, surface water and air: 50 in waste stage: 40
In-use stage (sealed articles)	< 3,000	+	80
In-use stage (open applications)	100	+	90

[1] -- = strong decrease, - = decrease, + = increase, ++ = strong increase, 0 = neutral

[2] Emissions relate to mixture/article production and mixture/article use. They do not include PFAS production and only for the formulation of lubricants also the waste stage of the articles. The emissions for PFAS production and the waste stage are also covered in a separate section.

V. Questions - Section C - Lubricants

Questions in relation to alternatives (mainly for individual companies)

Sub-Use	Non-PFAS alternatives
PTFE (micropowder)	- graphite - amorphous silica - molybdenum disulphide - boron nitride, other inorganics (e.g. layer building zinc phosphates) - water-based phenolic-melamine gold lacquer' alternative (still in R&D phase)
PTFE-thickened silicone oil for specific applications	- polyurea
High-bearing aromatic thermosetting polyester (ATSP) coating	- graphene

V. Questions - Section D - Lubricants

Questions in relation to impact of legislative measures (for companies and industry associations)

V. Questions - Section B - Construction products

Questions in relation to the use (mainly for industry associations)

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The following linked information presents the current picture: Report summary construction products july 2021.pdf

In the tables presented on this page and the following, '?' in the cells show that the authorities do not have any information available. Input to fill these gaps is highly appreciated.

Sub-Use	Tonnage (tonnes/PFAS) per year in the EEA	Expected trend (--/-/0/+/++)[1]	Emissions/year in EEA[2] (tonnes/PFAS)	
Polymeric PFAS	Formulation of articles and commercial construction mixtures	7,390	++ (5 - 8% for PTFE, PVDF, EFTE until 2030)	in soil, surface water and air: 330 in waste stage: 170
	In-use stage (outdoor articles)	3,270		in soil, surface water and air: 212
	In-use stage (indoor applications)	3,270		in soil, surface water and air: 2
	In-use stage (outdoor mixtures)	164		in soil, surface water and air: 9
	In-use stage (indoor mixtures)	150		in soil, surface water and air: 0.1
Non-polymeric PFAS	Formulation of articles and commercial construction mixtures	10,900	+ (1% for 2020 -2050)	in soil, surface water and air: 273 in waste stage: 163
	Use of processing aids	3,700		in soil, surface water and air: 5 in waste stage: 3,695
	In-use stage (outdoor articles)	1,712		in soil, surface water and air: 110
	In-use stage (indoor applications)	1,712		in soil, surface water and air: 1
	In-use stage (outdoor mixtures)	1,420		in soil, surface water and air: 91
	In-use stage (indoor mixtures)	1,502		in soil, surface water and air: 0.75

[1] -- = strong decrease, - = decrease, + = increase, ++ = strong increase, 0 = neutral

[2] Emissions relate to mixture/article production and mixture/article use. They do not include PFAS production and only in some cases the waste stage of the articles. The emissions for PFAS production and the waste stage are also covered in a separate section.

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V. Questions - Section C - Construction products
Questions in relation to alternatives (mainly for individual companies)

Sub-Use	Non-PFAS alternatives
Thermal insultation applications	- polyisocyanurate - phenolic thermal product
Processing aids in the production of construction products	? (only confidential information)
Architectural fabrics	- cotton and other natural fibres - polyamid (nylon) - polyester - fiberglass - aramid (Kevlar, Twaron) - carbon fibres
Fluoropolymer tube lining	- polypropylene - silicone - PVC
Paints and coatings	- polyurethane - polyester powder - wax emulsions - silicones/silanes/polysiloxanes - hydrocarbon polymer technologies
Coating additives	- hydrocarbon and silicone-based surfactants - short chain, polyether-modified siloxanes - low molecular weight polyether-modified siloxanes - siloxane multi-functional surfactants - alkoxylates (silicone and solvent-free)
Superhydrophobic coatings	- polymeric matrix (the binder) added to hydrophobic nanoparticles (the filler)
Wood primer and inks	- sulfosuccinates (e.g. sodium salt of di-(2-ethylhexyl) sulfosuccinate
Rust protection systems, marine paints,resins, printing inks and coatings in electrical applications	- propylated napthalenes - propylated biphenyls

V. Questions - Section D - Construction products
Questions in relation to impact of legislative measures (for companies and industry associations)
V. Questions - Section B - devices
Questions in relation to the use (mainly for industry associations)

Honeywell

The following linked information presents the current picture: Report summary medical devices july 2021.pdf

In the tables presented on this page and the following, '?' in the cells show that the authorities do not have any information available. Input to fill these gaps is highly appreciated.

Sub-Use[1]	Tonnage (tonnes/PFAS) per year in the EEA	Expected trend (--/-/0/+/++)[2]	Emissions/year in EEA[3] (tonnes/PFAS)
Anesthetics	2 - 1,000	+	~ 2 - 1,000
Contrast media	2 - 100	?	~ 2 - 100
Propellants	160 - 400	?	~ 160 - 400
MDI incl. F-gases	24,000 - 43,000	?	~ 4,200
Medical devices incl. packaging (mainly polymers)	3,700 - 14,000	?	90

[1] Contrast media, propellants and F-gases are mentioned here as medical devices.

[2] -- = strong decrease, - = decrease, + = increase, ++ = strong increase, 0 = neutral

[3] Emissions relate to mixture/article production and mixture/article use. They do not include PFAS production and the waste
stage of the articles. These emissions are covered in a separate section.

V. Questions - Section C - Medical devices
Questions in relation to alternatives (mainly for individual companies)
V. Questions - Section D - Medical devices
Questions in relation to impact of legislative measures (for companies and industry associations)
V. Questions - Section E - Medical devices
Specific questions for the use
V. Questions - Section B - Medicinal Products
Questions in relation to the use (mainly for industry associations)

The following linked information presents the current picture: Report summary medicinal products july 2021.pdf

In the tables presented on this page and the following, '?' in the cells show that the authorities do not have any information available. Input to fill these gaps is highly appreciated.

Sub-Use	Tonnage (tonnes/PFAS) per year in the EEA	Expected trend (--/-/0/+/++)[1]	Emissions/year in EEA[2] (tonnes/PFAS)
Medicines (human pharmaceuticals)	> 500[3]	+	> 500[3]
Medicines (veterinary pharmaceuticals)	?	?	?
Pharmaceutical intermediates[3]	8,200 (ECHA)	?	?

[1] -- = strong decrease, - = decrease, + = increase, ++ = strong increase, 0 = neutral

[2] Emissions relate to mixture/article production and mixture/article use. They do not include PFAS production and the waste stage of the articles. These emissions are covered in a separate section.

[3] The whole molecule/API is counted in this calculation.

V. Questions - Section C - Medicinal Products

Questions in relation to alternatives (mainly for individual companies)

V. Questions - Section D - Medicinal Products

Questions in relation to impact of legislative measures (for companies and industry associations)

V. Questions - Section E - Medicinal Products

Specific questions for the use

V. Questions - Section B - Metal plating & manufacturing of metal products

Questions in relation to the use (mainly for industry associations)

The following linked information presents the current picture: Report summary metal plating and manufacturing of metal products july 2021.pdf

In the tables presented on this page and the following, '?' in the cells show that the authorities do not have any information available. Input to fill these gaps is highly appreciated.

Sub-Use	Tonnage (tonnes/PFAS) per year in the EEA	Expected trend (--/-	Emissions/year in EEA[2] (tonnes/PFAS)

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		/0/+/++)[1]	
Metal plating	2 - 57 (6:2 FTS in chrome plating)	-	11.4 (6:2 FTS in chrome plating)
Manufacture of metal products	960 (fluoropolymers)	0	?

[1] -- = strong decrease, - = decrease, + = increase, ++ = strong increase, 0 = neutral

[2] Emissions relate to mixture/article production and mixture/article use. They do not include PFAS production and the waste stage of the articles. These emissions are covered in a separate section.

V. Questions - Section C - Metal plating & manufacturing of metal products

Questions in relation to alternatives (mainly for individual companies)

Sub-Use	Non-PFAS alternatives
Metal plating (here specifically chrome plating)	- alkane sulfonates - amines, C12-C14 alkyl, ethoxylated - oleo amine ethoxylates (e.g. mixtures with (Z)-octadec-9-enylamine, ethoxylated) - 3-[dodecyl(dimethyl) ammonio]propan-1-sulfonate (mixture with 3-hydroxypropane-1-sulfonic acid and amines, coco alkyldimethyl, N-oxides) - paraffin oils, sulfochlorinated, saponified - isodecanol, ethoxylated - chromium (III) plating - add-on air pollution control devices (e.g. packed bed scrubbers) - thermal spraying (e.g. high velocity oxygen fuel process) - physical vapour deposition - case hardening process (e.g. plasma nitriding) - laser metal deposition - anhydrous ionic liquids based on chromium (III)salts - closed coating reactors - nickel-based coatings - sulfonation of plastics with sulfur trioxide in the gas phase - acidic permanganate solutions, nitric acid and trichloroacetic acid mixtures
Manufacture of metal products	?

V. Questions - Section D - Metal plating & manufacturing of metal products

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Questions in relation to impact of legislative measures (for companies and industry associations)
V. Questions - Section E - Metal plating & manufacturing of metal products
Specific questions for the use
V. Questions - Section B - PFAS production (manufacturing)
Questions in relation to the use (mainly for industry associations)

The following linked information presents the current picture: Report summary production july 2021.pdf

In the tables presented on this page and the following, '?' in the cells show that the authorities do not have any information available. Input to fill these gaps is highly appreciated.

Sub-Use	Tonnage (tonnes/PFAS) per year in the EEA	Expected trend (--/-/0/+/++)[1]	Emissions/year in EEA[2] (tonnes/PFAS)
Fluoropolymers	Produced: 49,458 - 101,763 Imported: 36,148 (Eurostat) Exported: 28,718 (Eurostat)	+ (stakeholder)	in air: 10 - 20 in water: 3 - 6
F-gas	Produced: 13,600 - 52,800 Imported: 84,284 (Literature) Exported: 10,371 (Eurostat)	0 (stakeholder)	in air: 280 - 1,086 in water: 0.6 - 2.3
Remaining PFAS	Produced: 53,902 - 118,051 Imported: 103,586 (Eurostat) Exported: 131,866 (Eurostat)	+ (stakeholder)	in air: 11 - 24 in water: 3 - 7

[1] -- = strong decrease, - = decrease, + = increase, ++ = strong increase, 0 = neutral

[2] Emissions only relate to PFAS production. They do not include mixture/article production, mixture/article use and the waste stage of the articles. These emissions are covered in the other sections of this survey.

Do you have information that indicates that the information provided on the tonnage should be adjusted?

Yes

Please specify and/or refer to literature/public sources.

We do not manufacture in the EU however we would, as done in previous submissions refer you to the annual EEA report and would ask that adjustment if made to cover illegal HFC trade impact in some way.

Do you have information that indicates that the information provided on the emissions should be adjusted?

Honeywell

No

The environmental release category (ERC) is a key REACH use descriptor to define the release factors of a chemical substance in a specific use exposure scenario. It is used in various modelling tools to derive environmental exposure estimates. ERC default factors are used to estimate emissions of PFAS in three major life-cycle stages, namely the production stage including manufacture of substances, formulation of mixtures and production of articles, the 'in-use' stage, and the waste stage.

Please indicate if you have information on specific emission values (SPERCs) for (groups of) PFAS, based on measurements and / or model calculations.

We do not manufacture in the EU. That aside, the majority of our refrigerants do not fall under the SPERC system

Do you have information that indicates that the information provided on the expected trend should be adjusted?

Yes

Please specify and/or refer to literature/public sources.

As previously shared, we see future import/trade trends in HFOs, HFCs and their blends as in line with GDP, except for heat pumps where demand will run well ahead of this, driven in part by EU Green Deal. Given planned renovation wave in EU, we would also expect an increase in the demand for high performing foams containing HFOs given the move to deep renovation and increased standards.

Do you have information on risk management measures to minimize the use, human exposure and emissions to the environment?

Yes

Please specify and/or refer to literature/public sources.

We do not manufacture in the EU. However, our global operational emissions are less than 2% of total volumes on an annual basis, which is in accordance with industry standards. Emissions to water are very limited due to sophisticated supply chain. We will keep a strong continued focus to

continue to increase emission reduction across supply chain. RMM for the use and end-of-life stages are included in our replies in Sections B of this Questionnaire, where applicable.

V. Questions - Section C - PFAS production (manufacturing) Questions in relation to alternatives (mainly for individual companies)

Do you have the possibility to produce fluorinated polymers without fluorinated processing aids?

No

Please explain:

We do not manufacture in the EU.

V. Questions - Section D - PFAS production (manufacturing) Questions in relation to impact of legislative measures (for companies and industry associations)

What is the economic impact (in euro) and social impact (e.g. jobs) on your business/company if the use of PFAS is prohibited?

a) In 3 years.

Honeywell does not disclose this corporate information. However, we would expect that most of the jobs in the HFOs, HFCs and their blend industry sector and related sectors will be lost. Training programs, with substantial costs would be required. Honeywell's HFOs, HFCs and their blends business directly employ 600 people globally. We estimate that this business indirectly employs over 300-400 people in the EU. A sector report from JMS Consulting estimated the overall US jobs relating to HFOs, HFCs and their blends, and their downstream industries at 589,000 in the US in 2018. While we do not have exact equivalent estimates from Europe, we would expect the number of jobs in the EU to be similar.
https://www.alliancepolicy.org/site/usermedia/application/5/consumer_costs_final_inforumjms_20181110.pdf

b) In 10 years.

As above but deeper

c) Please explain by providing your calculations.

Honeywell does not disclose this information. However as already shared, there is a huge number of very different installed equipment/installations (e.g. cars, date canters, industrial and commercial refrigeration, etc.) with an economic life from 10-15 to over 40 years. Certain installations required very high investments and essential economic and social value for many people. Converting them to alternatives would require many billions of Euro and be severely constrained by the availability of technical staff as well as compatible equipment to do this. Drop-in replacements do not exist so the full system would need to be redesigned and replaced. Many of these solutions have a higher initial cost and have higher energy consumption resulting in higher overall cost to consumers. We expect

these costs will be passed on to the consumers in terms of e.g. higher food, accommodation, and energy costs. This will definitely impact and impeded the EU Green Deal objectives too.

What is the economic impact (euro) on your business/company, if the following measures will become mandatory? Please make your (indicative) calculations transparent.

a) A maximum concentration of e.g. 0.1% (or less) PFAS is set in mixtures and/or articles.

This is not specific as the quantity of product used depends upon the application. The levels are controlled by the GWP of the fluorinated product. The definition of PFAS will be critical. As per the RoI no fluorinated gas refrigerants or blends would be possible in the EU/EEA. As companies responsible for production/distribution the result would be complete closure with a loss to the EU economy of millions of Euro. This would also impact across the full value chain so beyond just producers and distribution.

b) Obligation to label your products visibly with "Contains PFAS".

Bulk products are already labelled as HFC and the GWP is also specified. The labelling of products and products-containing is under the F-gas Regulation Article 12 and is comprehensive. It is not easy to predict the economic impact of this measures if such a requirement is regulated twice in the context of a totally different regulatory framework

c) Obligation to report amount of PFAS in use and respective emissions.

Reporting requirements are already established in the F-Gas Regulation. Leakage control and record keeping have been key pillars since the first, 2006 F-Gas Regulation and they remained an important part of the 2014 revised F-Gas Regulation. Certain member states such as Poland, Italy, Estonia have showed very good practices in the context of logbook

d) Specific waste management requirements with the obligation to collect, treat or recycle PFAS containing waste separately.

Honeywell believes that this RMM (targeting end- of-life risks) are more appropriate risk mitigation option for F-gases then prohibitions on all PFAS. Coupled with voluntary production initiatives of relevant EU producers and users, these RMM could be the most effective risk mitigation as well as economically, technologically and societally neutral measures in practice. Although Honeywell is not a producer of respective final equipment/goods, we already provide customers (producers of HVAC and refrigeration equipment) with required information on traceability and safe use of Honeywell, incl. at waste stage (recuperation, recycling, disposal, etc.). Honeywell invests considerably in relevant R&D and on the ground support too. D2e) In case you are using PFAS polymers: no PFAS

processing aids are allowed during polymer production. N/A we do not use such aids in any manufacturing at a global level.

e) In case you are using PFAS polymers: no PFAS processing aids are allowed during polymer production.

N/A

V. Questions - Section E - PFAS production (manufacturing)

Specific questions for the use

If available, please provide data on the amount of fluorinated additives used in fluoropolymer production (kg/ton).

N/A

If available, please provide data on the tonnages used (yearly EEA) and applications of PTFE and PVDF micropowders.

N/A

If available, please provide information on the production of PFAS alternatives.

N/A

V. Questions - Section B - Ski treatment

Questions in relation to the use (mainly for industry associations)

The following linked information presents the current picture: Report summary ski treatment july 2021.pdf

Additionally, the Norwegian Environment Agency also published a short version of the report. This version can be accessed via the following link: PFAS in the treatment of skis - Use, Emissions and Alternatives

In the tables presented on this page and the following, '?' in the cells show that the authorities do not have any information available. Input to fill these gaps is highly appreciated.

Sub-Use	Tonnage (tonnes/PFAS) per year in the EEA	Expected trend /0/+/++)[1]	Emissions/year in EEA[2] (tonnes/PFAS)

Ski wax	1.64	-	in soil: 0.452 in surface water: 0.452 in air: 0.041 in waste stage: 0.695

[1] -- = strong decrease, - = decrease, + = increase, ++ = strong increase, 0 = neutral

[2] Emissions relate to mixture/article production and mixture/article use. They do not include PFAS production. The
emissions for PFAS production and the waste stage are also covered in a separate section.

V. Questions - Section C - Ski treatment

Questions in relation to alternatives (mainly for individual companies)

Sub-Use		Non-PFAS alternatives
Ski wax	Fluorine-free waxes	- hydrocarbon and paraffin waxes - siloxanes (but they are subject to environmental concerns) - nanoparticle-based waxes are being developed.
	Alterations to the ski itself	- a modified microstructure of the ski base - improved performance of the polyethylene of the ski - heating the base to obtain a better glide - controlling the vibrations of the ski

V. Questions - Section D - Ski treatment

Questions in relation to impact of legislative measures (for companies and industry associations)

V. Questions - Section E - Ski treatment

Specific questions for the use

V. Questions - Section B - TULAC (textiles, upholstery, leather, apparel and carpets)

Questions in relation to the use (mainly for industry associations)

The following linked information presents the current picture: Report summary TULAC july 2021.pdf

In the tables presented on this page and the following, '?' in the cells show that the authorities do not have any information available. Input to fill these gaps is highly appreciated.

Sub-Use	Tonnage (tonnes/PFAS)	Expecte trend	Emissions/year in EEA[2]

	per year in the EEA Low/High	(--/-/0/+/++)[1]	(tonnes/PFAS) Low/High
Home textiles	6,230/27,368	++	?
Consumer apparel	8,161/47,148	++	?
Professional apparel	5,220/20,044	++	?
Technical textiles	6,201/26,541	++	?
Medical applications	331/1,095	++	?
Leather	?	++	?
Other	15,041/20,496	++	?
Total	**41,184/142,692**	**++**	**4,933/18,103**

[1] -- = strong decrease, - = decrease, + = increase, ++ = strong increase, 0 = neutral

[2] Emissions relate to mixture/article production and mixture/article use. They do not include PFAS production and the waste stage of the articles. These emissions are covered in a separate section.

V. Questions - Section C - TULAC (textiles, upholstery, leather, apparel and carpets)

Questions in relation to alternatives (mainly for individual companies)

Sub-Use	Non-PFAS alternatives	
Home textiles	Carpets and rugs	- non-ionic polymer - ester compounds - hydrocarbon compounds, - organic solvent and water
	Curtains	- no specific substances found, see general textile (FF)
	Upholstery (e.g. fabrics for soft-furnishings, including large furniture items)	- hydrotreated heavy naphtha (petroleum) - non-ionic polymer, ester compound, hydrocarbon compound, organic solvent and water
Consumer apparel	Outdoor wear	- non-ionic polymer - ester compounds - hydrocarbon compounds

		- organic solvent and water - mixture of linear and branched hydrocarbons
	Indoor wear	?
	Sports wear	?
	Footwear	?
Professional apparel	Professional sports wear and footwear	?
	PPE for industrial applications e.g. for chemical workers, fire-fighters, O&G workers, law enforcement and	
Technical textiles	Outdoor technical textiles e.g. canvas, awnings, tarps, tents, bags, sails, rope, umbrellas	?
	Medical applications "non-woven", e.g. surgical drapes, gowns, curtains	
	High performance membranes e.g. automotive	

Textile in general (multiple sub-category uses)		- paraffin - non-ionic polymer - ester compounds - alcohols, C12-16, ethoxylated (>5-15 EO) - hydrocarbon polymer dispersion - aqueous preparation of polymer waxes - paraffin oils and a fat modified melamine resin - dispersion of paraffin wax and acrylic copolymer - paraffin oils and a fat modified melamine resin and blocked polyisocyanates - dispersion of paraffin oils and a fat modified melamine resin - naphtha (petroleum), hydrotreated heavy, - modified wax dispersion - (bee-) wax - carnauba wax - acrylate copolymer - dispersion of fat-modified chemicals and paraffin - plant seed oil, bio based product - acrylic polymer and paraffin dispersion - acrylic polymer and silicone reactive dispersion - acrylic polymer, reactive silicone and paraffin dispersion - functionalised polymers/waxes, cationic - emulsifier-free paraffin wax - emulsion containing aluminum - acrylic polymer and dispersion of fatty derivatives - polyethylene oxide mono-C12-16-alkyl ether - aminofunctional PDMS - sodium methylsiliconate water - potassium methylsiliconate - isobutyltrimethoxy silane - octylsilane - hexyltriethoxysilane - blend of n-octyltriethoxysilane and reactive silicone, octyltrimethoxysilane-based - methoxy terminated silsesquixanes - emulsion of polydimethylsiloxane - cationic polysiloxane and polyester - polysiloxane - mixtures of silicones and stearamidomethyl pyridine chloride, sometimes together with carbamide (urea) and melamine resins - aminofunctional polysiloxanes - water-based silicone emulsion - solvent-dilutable silicone solution - siloxane dispersion with modified polyamide,

		- acrylic polymer and silicone reactive dispersion - dodecamethyl pentasiloxane (PDMS) - aqueous, solvent free dendrimers - anionic dispersion of an aliphatic polyether urethane - polyurethane emulsion, water-based - anionic dispersion of a matt polyether polyurethane, water-based, solvent free - anionic dispersion of an aliphatic polycarbonate urethane - plasma based nano-coating, molecularly attached hydrophobic 'whiskers' attached to individual fibres, uses a hydrocarbon polymer
Leather	Leather in general	- hybrid (silicone/hydrocarbon) - solvent-dilutable silicone solution - water-based silicone emulsion
Other	Home fabric treatments (sprays)	- alkyl polysiloxane solution

V. Questions - Section D - TULAC (textiles, upholstery, leather, apparel and carpets)
Questions in relation to impact of legislative measures (for companies and industry associations)
V. Questions - Section E - TULAC (textiles, upholstery, leather, apparel and carpets)
Specific questions for the use
V. Questions - Section B - Petroleum & mining
Questions in relation to the use (mainly for industry associations)

The following linked information presents the current picture: Report summary petroleum and mining july 2021.pdf

Additionally, the Norwegian Environment Agency also published a short version of the report. This version can be accessed via the following link:PFAS in mining and petroleum industry – use, emissions and alternatives

In the tables presented on this page and the following, '?' in the cells show that the authorities do not have any information available. Input to fill these gaps is highly appreciated.

Sub-Use	Quantity of product used (t)	Tonnage (tonnes/PFAS) per year in the EEA	Expected trend (--/-/0/+/++)[1]	Emissions/year in EEA[2] (tonnes/PFAS)

Water and gas traces	1	1	0[3]	in soil: 0 - 0.005 in water: 0.020 - 0.025 in marine water: 0 - 0.110 in air: 0.025 - 0.070 in waste stage: 0.020 - 0.145
Drilling/Production chemicals	170	3 - 8	0[3]	in soil: 0 - 0.045 in water: 0.070 - 0.210 in marine water: 0.020 - 0.760 in air: 0.085 - 0.635 in waste stage: 0.015 - 0.230
Fluoropolymers (all) Low scenario[4]	3,500 - 7,500.5	0.004 - 0.008 monomeric PFAS	0[3]	in soil: < 0.001 in water: < 0.001 in marine water: < 0.001 in air: 0.001 - 0.002 in waste stage: 0.001 - 0.003
Fluoropolymers (all) High scenario[5]	3,500 - 7,500.5	0,9 - 1,9 monomeric PFAS	0[3]	in soil: 0 .020 - 0.045 in water: 0.003 - 0.006 in marine water: 0.020 - 0.040 in air: 0.270 - 0.580 in waste stage: 0.310 - 0.670

[1] -- = strong decrease, - = decrease, + = increase, ++ = strong increase, 0 = neutral

[2] Emissions relate to mixture/article production and mixture/article use. They do not include PFAS production.

[3] Conservative annual growth of 1%.

[4] 1 ppm monomeric PFAS in fluoropolymers (Lohmann et al., 2020).

[5] 0-2000 ppm monomeric PFAS in fluoropolymers (Ökopol 2014 and used in PFOA restriction).

V. Questions - Section C - Petroleum & mining

Questions in relation to alternatives (mainly for individual companies)

Honeywell

Sub-Use	Non-PFAS alternatives
Water and gas tracers	- radioactive tracers - noble gas isotopic tracer - xenon - radiolabelled compounds
Drilling and production (antifoaming)	- polydimethylsiloxane (PMDS) oils - ethyl siloxanes - polypropylene glycol - naphthalene/1,2,4-trimethylbenzene based products - dipropylene glycol monomethyl ether - 2,6-dimethylheptan-4-one.
Fluoropolymers	- steel - other metal alloys - non-metal materials (ceramic or epoxy based) - cross-linked polyethylene (XL PE) - polyamides such as ethylene propylene diene (EPDM) - hydrogenated nitrile Rubber (HNBR) - polyether ether ketone (PEEK)

V. Questions - Section D - Petroleum & mining

Questions in relation to impact of legislative measures (for companies and industry associations)

V. Questions - Section E - Petroleum & mining

Specific questions for the use

V. Questions - Section B - F-gas uses

Questions in relation to the use (mainly for industry associations)

The following linked information presents the current picture: Report summary F gas uses july 2021.pdf

Additionally, the Norwegian Environment Agency also published a short version of the report. This version can be accessed via the following link: Application of Fluorinated Gases (F-Gases) in the European Economic Area

In the tables presented on this page and the following, '?' in the cells show that the authorities do not have any information available. Input to fill these gaps is highly appreciated.

Sub-Use	Tonnage (tonnes/PFAS	Expecte trend	Emissions/year in EEA$_2$

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	per year in the EEA	(--/-/0/+/++)[1]	(tonnes/PFAS)[3] all emissions to air for F-gases
Domestic refrigeration	122	0	17
Commercial refrigeration	7,915	+	9,547
Industrial refrigeration	2,360	-	3,680
Transport refrigeration	1,010	0	1,341
Mobile air conditioning	5,221	++	11,726
Stationary air conditioning and heat pumps	7,465	++	7,458
Foam blowing agent (closed cell)	4,940	+	4,186
Foam blowing agent (open cell)	271	0	1,074
Fire protection	863	0	703
Propellants (non-MDI)	504	-	701
Solvents	?	0	> 11
Cover gas for magnesium casting	?	+	> 23
Other	?	?	35

[1] -- = strong decrease, - = decrease, + = increase, ++ = strong increase, 0 = neutral

[2] Emissions relate to mixture/article production and mixture/article use. They do not include PFAS production and the waste
stage of the articles. These emissions are covered in a separate section.

[3] Due to large tonnages in stock, emissions can be higher than annual tonnage.

Do you have information that indicates that the information provided on the tonnage should be adjusted?

Yes

Please specify and/or refer to literature/public sources.

We do not recognize these numbers and see them somewhat at odds with existing market knowledge reports e.g. EEA report and input from trade association. They also contradict some of the figures presented in other expert reports in the CfE (e.g. transportation). It is not clear if and how any of this data was retrieved. Your market data on F-gases filled into new products and in stocks

each year appears to be primarily sourced through data collated by the EU/EEA Govts in UNFCCC report (EU, 2020a).

Do you have information that indicates that the information provided on the emissions should be adjusted?

Yes

Please specify and/or refer to literature/public sources.

The market data on F-gases filled into new products and in stocks each year appears to be primarily sourced through data collated by the EU/EEA Govts in UNFCCC report (EU, 2020a). However, the cited data clearly stems from different sources. Emissions and tonnage should be aligned to the most recent values and should also reflect the scope of the existing monitoring and reporting requirements of Regulation 525/2013 on a mechanism for monitoring and reporting greenhouse gas emissions to better align with existing obligations. We recommend covering TFA potentially generated in the atmosphere from the breakdown of some individual HFCs and HFOs in these emissions. As the concern over the use of fluorinated gas is mainly related to the atmospheric breakdown to generate TFA and the potential addition of this TFA to the large natural background of TFA, any restriction analysis must focus on the generation and increase in the environment of the **“persistent product' above natural level.**

Do you have information that indicates that the information provided on the expected trend should be adjusted?

Yes

Please specify and/or refer to literature/public sources.

Market trend data was already shared in the last survey. Growth will be in line with GDP –more detailed predictions can be found in different market reports such as here In view of the decarbonization agenda, the planned change over from natural gas and fossil fuel heating will lead to an increase in the use of heat pumps, these are largely dependent on HFOs, HFCs and their blends. An increase in use is also expected for high performing foams containing HFOs given the move to deep renovation and increased standards.

Do you have information on risk management measures to minimize the use, human exposure and emissions to the environment for your application of PFAS?

Yes

Please specify and/or refer to literature/public sources.

F-gases are used in closed systems and recovered at the end-of-life in accordance with risk management measures (RMM) via various EU regulations (e.g. F-Gas Regulation , MAC Directive, CPR (Construction Products Regulation), WEEE Directive, ELV Directive and others). Core RMM are provided in the F-Gas Regulation. This Regulation, details leakage checks on certain equipment as well as a phase-down schedules plus restrictions on applications. Article 6 specifies detailed records that must be kept and retained by operators of equipment and must be available to the competent authorities of the Member States. Consultation with individual Member States should enable a complete analysis of the actual leakage/emissions from equipment and demonstrate the effectiveness of these measures. Other broader RMM are the following Directives: Eco-design, General Product Safety, Low Voltage, ATEX Workplace and the Industrial Emissions as well as the Pressure Equipment, Machinery Seveso and standards.

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V. Questions - Section C - F-gas uses

Questions in relation to alternatives (mainly for individual companies)

Sub-Use	Non-PFAS alternatives
Domestic refrigeration	- iso-butane - propane (not in-kind refrigeration cycles)
Commercial refrigeration	- CO_2 - isobutane - propane
Industrial refrigeration	- CO_2 - ammonia - n-butane
Transport refrigeration	- CO_2 - ammonia - CO_2 with N_2 as direct coolant - propane (not in-kind: advanced cool box storage)
Mobile air conditioning	- CO_2 - propane
Stationary air conditioning and heat pumps	- CO_2 - ammonia - propane
Foam blowing agent (closed cell)	Depending on the specific application: - cyclopentane - iso-pentane - n-pentane - isobutane - n-butane - 2-chloropropane - dimethyl ether (DME) - methyl formate - methylal - CO_2/ methyl formate - CO_2(water) - CO_2(liquid) - CO_2/ ethanol - water blown foams
Foam blowing agent (open cell)	
Fire protection	- inert gases (nitrogen and argon) - CO_2 - water mist technologies - inert gas generators - fine solid particle technology

	- dry chemical agents - water and aqueous salt solutions
Propellants (non-MDI)	Compressed gases: - air - nitrogen - nitrous oxide - CO_2
	Liquefied gases: - butane - propane - isobutane - dimethyl ether
	Not-in-kind alternatives: - trigger sprays - finger pumps - squeeze bottles - non-sprayed products including roll-ons - bag-on-valve products
Solvents	Depending on the specific application: - isopropyl alcohol (IPA) - n-Propyl bromide - dichloromethane - trans-1,2-dichloroethylene - trichloroethylene (TCE) - perchloroethylene (PER) - volatile methyl siloxanes - hydrocarbons (hexane, heptane, benzene) - acetone - semi-aqueous / aqueous cleaning - manual cleaning methods (aerosols, brush, trigger spray, liquid immersion, spot cleaning, wipes) - ultrasonic - plasma cleaning - supercritical fluids – CO_2 - no clean fluxes
Cover gas for magnesium casting	- SO_2 - argon - salt fluxes - powdered sulfur

What is the specific application/functionality of PFAS in your product(s)/processes?

Honeywell produces and sells 1) refrigerants to the HVAC system and/or equipment manufactures; 2) industrial solvents (suitable for metal, medical, and electronics cleaning in vapor degreasing equipment and aerosol applications, as well as line flushing); 3) blowing agents, which are used in the manufacture of foam; and 4) aerosol propellants. This covers the full line of traditional HFCs and HFC blends as well as HFOs and HFO blends. Customers after careful consideration and evaluation choose these solutions (i.e., HFOs, HFCs and their blends) for regulatory compliance, safety, best efficiency, performance and total cost of ownership. The use of our products is across a huge range of applications you can find more detail on which ones here: https://www.fluorocarbons.org/applications/

Are in your view the listed non-PFAS alternatives technically feasible in your product(s)/processes?

No

Please specify why.

The listed alternatives cannot cover the entire market due to several safety concerns, building codes, energy efficiency requirements, and installation limitations due to the lack of expertise, training and certification. This is about the overall performance of each refrigerants and its interlinkage to climate and decarbonization goals. The table of sub-uses does not provide a comprehensive use guidance to alternatives. Refrigeration and Air-conditioning use must be broken down into a larger number of sub-sectors (report and annex in 2011 Preparatory study for a review of Regulation (EC) No 842/2006 on certain fluorinated greenhouse gases Final Report Prepared for the European Commission in the context of Service Contract No 70307/2009/548866/SER/C4). Many of these sub-sectors are unique and the alternatives must be selected on a case-by-case basis. The list of alternatives for the sub-sectors does not include fluorocarbon alternatives and is, therefore, incomplete.

Are in your view the listed non-PFAS alternatives economically feasible in your product(s)/processes?

No

Please specify why.

The listed non-PFAS alternatives cannot cover the entire market due to several safety concerns, building codes, energy efficiency requirements, and installation limitations due to the lack of expertise, training and certification. Any analysis must include the energy efficiency of the alternatives and the measures required to operate equipment safely. A REACH restriction focuses on the emissions of products to the environment. There will equally be similar emissions from equipment for non-fluorocarbon alternatives some of which are flammable (e.g., hydrocarbons) or hazardous (e.g., ammonia) to health. It risks undermining EU Green Deal objectives (as well as would result in huge R&D cost for development/replacement of new equipment. Given diverse physico-chemical properties and multi-sectoral uses of F-gases, a substance-by-substance analysis as well as appliance-by-appliance assessment of their uses and available alternatives as mandated by REACH.

Do you have information on the alternatives' risk profile?

Yes

Please describe.

While there may be an apparent price advantage in the use of some alternatives (e.g. CO2), that is outweighed by the higher engineering cost to meet regulatory and safety requirements: equipment costs and life-time operating (e.g., energy and maintenance) costs. The supply and use of alternatives are subject to safety restrictions associated with toxicity (ammonia), extreme flammability (hydrocarbons) and very high operating pressures. Most of the production of alternatives and the raw materials used in their production (except water which has limited applicability) are embedded with fossil fuel production. This is therefore at odds with EU Zero Emissions approach and the Paris Agreement.

Are there legal approval schemes for your product(s)/processes, which have to be taken into account in case PFAS alternatives will be used?

Yes

Please specify and/or refer to literature/public sources.

There are numerous technical regulations and standards relevant for F-gases applications in every and each sector. For example, use of F-gases in refrigerating systems and heat pumps in the EU (incl. safety and environmental requirements) is subject to the CEN EN 378 standard series, harmonized with the international ISO 5149 standards. Use of refrigerants in road vehicles systems (MAC and heating both passengers, battery, etc.) are subject to updated ISO 13043 standard series. These standards address the use of R-134a, R-1234yf and R-744 (CO2) refrigerants in vehicle original equipment manufacturer (OEM) and aftermarket (non-OEM) supplied components and systems. National/regional standardization bodies around the world base respective national technical regulations on the above ISO standards. There are relevant ISO, CEN and industry specific standards covering all sectors concerned.

What is the average approval time?

Research and development of suitable alternative non-fluorinated substances (if any) will take minimum – 10 years. Same time is required for development and approval of various equipment (MAC, chillers, heat pumps, etc.). However, please note that the existing HFC/HFO equipment would need to come to the end of its service life before non-F-gas systems were developed and adopted. For small appliances and vehicles this may be a period of 10-15 years whilst for some industrial, commercial and essential infrastructure applications it may take much longer, i.e. over 40 years. In case of shorter periods economic and social consequences would be even difficult to imagine.

Do you actively work on finding alternatives?

No

If alternatives have been identified as potentially suitable, which timescale do you foresee for a complete transition to those? Please explain.

N/A

Do you have information on additional alternatives for any of the described applications that have not been disclosed in the attached information?

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N/A

V. Questions - Section D - F-gas uses
Questions in relation to impact of legislative measures (for companies and industry associations)
What is the economic impact (in euro) and social impact (e.g. jobs) on your business/company if the use of PFAS is prohibited?

a) In 3 years.

The prohibition of F-gases would result in a complete shut-down of the production/distribution of affected products. For new equipment: Measures in current F-gas Regulation specify a timetable to 2030. Investment and planning have been made by producers and down-stream users to take into account this timetable. A prohibition in less than this period would cause a complete disruption of the transition from higher-GWP products and could result in issues for the EU climate change ambitions. For existing equipment: this would need to come to the end of its service life before non-F-gas systems were adopted. For small appliances and vehicles this may be a period of 10-15 years whilst for some industrial and commercial applications it may take much longer up to 40 years. With a rapid transition (e.g. 3 years), there is potential for significant immediate disruption to the market. The market moves towards alternatives whenever this is possible from a safety, energy efficiency and affordability

b) In 10 years.

Refrigerant choice depends on many different factors and still mainly determined by technology and application. In ten years: The prohibition of F-gases would result in a complete shut-down of the production and distribution of the affected products. A PFAS REACH restriction for F-Gases would also affect the import and export market, due to the full ban on use, manufacture and place on the market. Several factories will relocate their manufacturing plants from EU to third countries outside EU, due to difficulties to compete on the global export market. The market moves towards alternatives whenever this is possible from a safety, energy efficiency and affordability perspective.

c) Please explain by providing your calculations.

as above

What is the economic impact (euro) on your business/company, if the following measures will become mandatory? Please make your (indicative) calculations transparent.

a) A maximum concentration of e.g. 0.1% (or less) PFAS is set in mixtures and/or articles.

A maximum concentration of e.g. 0.1% (or less) PFAS is set in mixtures and/or articles. This is not specific as the quantity of product used depends upon the application. The levels are controlled by the GWP of the fluorinated product. The definition of PFAS will be critical. As per the RoI no fluorinated gas refrigerants or blends would be possible in the EU/EEA. As companies responsible for production/distribution the result would be complete closure with a loss to the EU economy of hundreds of millions of Euro. This would also impact across the full value chain so beyond just producers and distribution.

b) Obligation to label your products visibly with "Contains PFAS" .

Bulk products are already labelled as HFC and the GWP is also specified. The labelling of products and products-containing is under the F-gas Regulation Article 12 and is comprehensive. It is not easy to predict the economic impact of this measures if such a requirement is regulated twice in the context of a totally different regulatory framework.

c) Obligation to report amount of PFAS in use and respective emissions.

Reporting requirements are already established in the F-Gas Regulation. Leakage control and record keeping have been key pillars since the first, 2006 F-Gas Regulation and they remained an important part of the 2014 revised F-Gas Regulation. Certain member states such as Poland, Italy, Estonia have showed very good practices in the context of logbooks

d) Specific waste management requirements with the obligation to collect, treat or recycle PFAS containing waste separately.

The F-Gas Reg is the main framework to complement the general waste framework Directive (WFD) in relation to F-gases and establishes recovery, recycling and reclamation (RRR) requirements for F-gases already since 2006. The same is true under the EU MAC Directive. The above, as well as other measures on certification and training in F-Gas Regulation play a key role in reducing emissions and are fully in line with the objectives of the EU circular economy and ensure the correct treatment and disposal of F-gases including PFAS. WEEE Directive Annex VII requiring removing substances, mixtures and components, having a GWP>145 such as HFC, to be properly extracted and treated. It should however be noted that HFO-HFC suppliers have been actively investing in reclaim in reclaim facilities unlike suppliers of e.g., alternatives refrigerants.

e) In case you are using PFAS polymers: no PFAS processing aids are allowed during polymer production.

N/A we do not use such aids in our manufacturer anywhere in the globe.

V. Questions - Section E - F-gas uses
Specific questions for the use

Do you have information on the use of F-gases apart from the ones considered so far (heating/ventilation/air conditioning/refrigeration, foam blowing agents, propellants,

solvents, fire suppression, and as cover gas), like e.g. in electronics cooling/data centers or use as solvents in 3D printing?

No

V. Questions - Section B - Electronics & energy Questions in relation to the use (mainly for industry associations)

The following linked information presents the current picture: Report summary electronics and energy july 2021.pdf

In the tables presented on this page and the following, '?' in the cells show that the authorities do not have any information available. Input to fill these gaps is highly appreciated.

Sub-Use	Tonnage (tonnes/PFAS) per year in the EEA	Expected trend (--/-/0/+/++)[1]	Emissions/year in EEA (tonnes/PFAS)
Electronics industry and semiconductor	Non-Polymers: 1,200 Polymers: 3,100 Total: 4,300	++	Production: 700 Use: 20 Recycling / waste: 900
Semiconductor	Non-Polymers: 85 Polymers: 1,400 Total: 1,485	++	
Energy industry	Non-Polymers: 250 Polymers: 1,200 Total: 1,450	++	Production: 40 Use: 1 Recycling / waste: > 24
Batteries	Polymers: 15,000	++	Production: ? Use: ? Recycling: ?

[1] -- = strong decrease, - = decrease, + = increase, ++ = strong increase, 0 = neutral

V. Questions - Section C - Electronics & energy Questions in relation to alternatives (mainly for individual companies)

Sub-Use	Non-PFAS alternatives
Electronics industry and semiconductor	For fluoroelastomers in sealing: ethylene propylene diene monomer (EPDM) and silicone rubbers For wire insulation: ilicone materials

Honeywell

Sub-Use	Non-PFAS alternatives
	Polyetheretherketone (PEEK) For photolithography (hard and not for all applications): hydrocarbon-based greases, Molybdenum disulfide, graphite
Energy industry	For fluoropolymer-based backsheets for photovoltaic cells polyolefin could be an alternative. Other fluorine free backsheets made of polyethylene terephthalate (PET) and/or ethylene vinyl acetate (EVA) can/are also used For cables: Mica and EPDM For seals: Hydrocarbon elastomers For batteries :Solid-state batteries For fuel cells: For PEM membranes: Hydrocarbon membrane and sulphonated Reinforcement material as alternative to PTFE: Electrospun polybenzimidazole-type materials For sealings: Some elastomers without fluorine exist and could potentially be used in the future for the Membrane Electrodes Assembly (MEA) function For immersion cooling: Synthetic oil

V. Questions - Section D - Electronics & energy
Questions in relation to impact of legislative measures (for companies and industry associations)
V. Questions - Section E - Electronics & energy
Specific questions for the use
V. Questions - Section B - Transportation
Questions in relation to the use (mainly for industry associations)

The following linked information presents the current picture: Report summary transportation july 2021.pdf

In the tables presented on this page and the following, '?' in the cells show that the authorities do not have any information available. Input to fill these gaps is highly appreciated.

Sub-Use	Tonnage (tonnes/PFAS)	Expected trend (--/-	Emissions/year in EEA[2]

	per year in the EEA	/0/+/++)[1]	(tonnes/PFAS)	
Body-, hull and fuselage construction	?	0	?	
Sealing applications	111,104 (fluoroelastomers in road transportation vehicles)	0	?	
Lubrication	?	0	?	
Hydraulic fluids	?	0	?	
Electrical engineering and information technology	?	++	?	
Coating and finishings (incl. textiles, interiors and related applications, e.g. coating of trim materials)	?	+	?	
HVACR systems (heating, ventilation, air conditioning and refrigeration)	F-gases in road transportation vehicles	184,130	+	9,000
	F-gases in systems in trains/ships/aircrafts	?	+	?
	F-gases in systems for transport refrigeration	10,926	+	495.8
Health protection and lifesaving equipment (incl. firefighting, life vests, life rafts, airbags, ...)	?	+	?	

[1] -- = strong decrease, - = decrease, + = increase, ++ = strong increase, 0 = neutral

[2] Emissions relate to mixture/article production and mixture/article use. They do not include PFAS production and the waste
stage of the articles. These emissions are covered in a separate section.

Do you have information that indicates that the information provided on the tonnage should be adjusted?

No

Do you have information that indicates that the information provided on the emissions should be adjusted?

No

Do you have information that indicates that the information provided on the expected trend should be adjusted?

No

Do you have information on risk management measures to minimize the use, human exposure and emissions to the environment for your application of PFAS?

No

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V. Questions - Section C - Transportation

Questions in relation to alternatives (mainly for individual companies)

Sub-Use	Non-PFAS alternatives
Body-, hull and fuselage construction	?
Sealing applications	?
Lubrication	?
Hydraulic fluids	?
Electrical engineering and information technology	?
Coating and finishings (incl. textiles, interiors and related appliactions, e.g. coating of trim materials)	- silicone based chemicals - sulfosuccinates - propylated aromatics - fatty alcohol polyglycol ether sulphates - alkyl acrylates - polyurethanes and -acrylics
HVACR systems (heating, ventilation, air conditioning and refrigeration)	- air - water - ethylene glycol - mineral oils - silicone oils - alcohols - natural gases: HC-600 (n-butane), R-717 (Ammonia), R-744 (CO_2)
Health protection and lifesaving equipment (incl. firefighting, life vests, life rafts, airbags, ...)	?

What is the specific application/functionality of PFAS in your product(s)/processes?

F-gases HFO/HFC are refrigerants in standard Mobile Air Conditioning (MAC), heating (HVAC) and Electric Vehicle (EV) Thermal Management Systems (TMS) which include battery, motor and inverter cooling and heat pumps. These refrigerants are also used in transportation refrigeration (in tracks, containers, etc.) by all means of transport – road, railway, sea and other waterways, and air. Furthermore, these refrigerants are essential for electrified mobility. Every traction battery needs proper cooling and heating for safe operation, quick charging, efficient storage and providing electric power supply on customer demand.

Are in your view the listed non-PFAS alternatives technically feasible in your product(s)/processes?

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No

Please specify why.

So called “natural refrigerants” such ammonia and hydrocarbons are manufactured chemical substances with important hazard and exposure characteristics including toxicity, anaesthetic effects and/or high flammability. Their use in transportation sector entails very high safety and health risks incomparable with modern HFO/HFC refrigerants. The only possible alternative is CO2, which has the following concerns: 1)Pressure 10 times higher operational pressure require complete redesign and retooling of all major AC components; 2) Safety servicing vehicles with these high pressures increases the likelihood of accidents. Shrapnel and fragmentation of AC components in the event of a collision; 3) Reliability Retaining CO2 in the refrigerant system is a challenge given the small molecule size and higher pressures needed. More frequent refrigerant servicing would be required and can reduce overall efficiency when low charge conditions exist (particularly in EVs) CO2 performance in high temps.

Are in your view the listed non-PFAS alternatives economically feasible in your product(s)/processes?

No

Please specify why.

Major CO2 refrigerant cost challenges in vehicles are: - 1. Cost - Higher costs for both manufacturers and consumers will have a societal impact, based on both economies of scale and premium materials or structural requirements to maintain the higher pressures. 2. Performance in hot weather - CO2 as a refrigerant in automotive MAC/HVAC systems loses efficiency in hot weather conditions which can increase fuel usage (and CO2 tailpipe emissions) and reduce EV range based on cooling needs. Energy consumption for MAC AC usage has been estimated to be three times higher in hot climates as opposed to more temperate conditions. Given increasing climate temperatures due to global warming this problem will become even more problematic in the near future. The above problems make CO2 technically concerning and economically undesirable to implement in MAC/HVAC systems at the required scale and level of safety. Overall effects of such changes on consumers’ satisfaction and GHG emissions would be

Do you have information on the alternatives' risk profile?

Yes

Please describe.

So called “Natural refrigerants” such as R-744 (CO2), ammonia and hydrocarbons (propane, isobutene, etc.) are manufactured chemical substances with important hazard and exposure characteristics including toxicity (i.e. ammonia, hydrocarbons), anaesthetic effects (CO2) and/or high flammability (i.e. hydrocarbons). Most of the production of these alternatives and the raw materials used in their manufacturing are embedded with fossil fuel production. Promotion of these substances is at odds with the EU Green Deal and the Paris Agreement objectives.

Are there legal approval schemes for your product(s)/processes, which have to be taken into account in case PFAS alternatives will be used?

Yes

Please specify and/or refer to literature/public sources.

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Main international standards for transportation MAC/HVAC and TMS systems are ISO 13043 standard series. Before admission on roads vehicles (including all on board equipment) should also obtain the EC or national type-approval conformity procedure. Annual technical control of all critical systems is also obligatory for vehicles after certain age. In commercial passenger and cargo transportation the above controlling procedures are very strict and regular.

What is the average approval time?

Based on the experience, the average approval time is as follows: • ASHRAE and ISO817 registration: typically, ~12-18 months • Vehicle type approval: typically, ~24-48 months after ASHRAE registration Consideration should also be given to the timeframe required to allow continued F-Gas supply for maintenance. An example could be taken from article 6 of the MAC directive (Directive 2006/40/EC), where the provision allowed for an overall period of about 11 years (since the directive adoption in May 2006 until January 1st, 2017) the retrofitting and refilling of vehicles.

Do you actively work on finding alternatives?

No

Do you have information on additional alternatives for any of the described applications that have not been disclosed in the attached information?

There are several pilot MAC/HVAC/TMS systems with CO2 worldwide. However, they require a lot of resources and time (min 10-15 years) to be commercialized at scale. Average services life of vehicles is 10-15 years during this time constant supply of fluorinated refrigerants is essential.

V. Questions - Section D - Transportation
Questions in relation to impact of legislative measures (for companies and industry associations)
What is the economic impact (in euro) and social impact (e.g. jobs) on your business/company if the use of PFAS is prohibited?

a) In 3 years.

The scope of PFAS within the prohibition is critical. As per the current RoI no fluorinated gas refrigerants or blends would be possible in the EU/EEA. Companies responsible for production/distribution would close the business completely with a loss to the EU economy of hundreds of millions of Euro. This would also impact across the full value chain so beyond just producers and distributors of PFAS, e.g., in transportation sector. In case of an immediate PFAS ban rapid deterioration of the EU private/commercial passenger and cargo transportation sector is very probable

b) In 10 years.

Ten-year period in not enough to ensure smooth transition to non-fluorinated refrigerants in transportation sector. Minimum ten years are need just to develop and launch commercialization of

alternative MAC/HVAC and TMS systems in road transportation sector. Considering specifics of other means of transport, this period should be minimum 15 years. During this time constant supply of F-gases is needed for the normal function of the overall EU transportation sector.

c) Please explain by providing your calculations.

As above

What is the economic impact (euro) on your business/company, if the following measures will become mandatory? Please make your (indicative) calculations transparent.

a) A maximum concentration of e.g. 0.1% (or less) PFAS is set in mixtures and/or articles.

This is not specific as the quantity of product used depends upon the application. The levels are controlled by the GWP of the fluorinated product. With current RoI scope of potential restrictions no fluorinated gas refrigerants or blends in transportation sector would be possible in the EU/EEA. See reply to Questions above.

b) Obligation to label your products visibly with "Contains PFAS".

Bulk products are already labeled as HFC with the GWP specification. The labelling of products and products-containing under the F-gas Regulation Article 12 is comprehensive. It is not easy to predict the economic impact of this measures if such a requirement is regulated twice in the context of a totally different regulatory framework.

c) Obligation to report amount of PFAS in use and respective emissions.

Reporting requirements are already established in the F-Gas Regulation. Leakage control and record keeping have key pillars since the first, 2006 F-Gas Regulation and they remained an important part of the 2014 revised F-Gas Regulation. MAC Directive 2006/40/EC also provide for obligations on leakage control. Certain member states such as Poland, Italy, Estonia have showed very good practices in the context of logbooks. D2d) Specific waste management requirements with the obligation to collect, treat or recycle PFAS containing waste separately. The F-Gas Regulation is the main framework to complement the general waste framework Directive (WFD) in relation to F-gases and establishes very detailed recovery, recycling and reclamation (RRR) requirements for F-gases including PFAS, already since the first 2006 F-Gas Regulation was adopted. The same is true under the EU MAC Directive.

d) Specific waste management requirements with the obligation to collect, treat or recycle PFAS containing waste separately.

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Today, recycling requirements applicable to Automotive OEMs are to be found in the ELV Directive, annex I is describing ELV fluid removal requirements for example, the refrigerant is being collected as part of the pretreatment process during the end-of-life phase of the vehicle. Also, here the refrigerant is returned to the gas supplier for reclamation or disposal.

e) In case you are using PFAS polymers: no PFAS processing aids are allowed during polymer production.

N/A

V. Questions - Section E - Transportation

Specific questions for the use

For this restricton proposal the assessment of the transportation sector encompassess: road traffic, ships, trains and aircrafts. We identified the following applications of PFAS in the transportation sector:

1.) Body-, hull and fuselage construction
2.) Sealing applications
3.) Lubrication
4.) Hydraulic fluids
5.) Electrical engineering and information technology
6.) Coating and finishings (incl. textiles, interiors, and related applications e.g. coating of road signs)
7.) HVACR systems (heating, ventilation, air conditioning and refrigeration)
8.) Health protection and life saving equipment (incl. fire prevention and fire fighting)

Are applications missing in the overview above? If so, please name them. Where possible, refer to literature/public sources.

Report summary transportation does not address at all uses of F-gases as refrigerants in cargo containers, fishery industries, air fleet, sea and river vessels. These albeit 'niche' applications are critical for the modern society and require detailed considerations. If not properly addressed, PFAS prohibitions would certainly and severally affect the above sectors and escalate costs on the society.

What would be a realistic timeframe and realistic costs in case standards need to be adjusted?

By its nature, transportation sector is mainly subject to international standards established by international/regional industry organizations and conventions (OECD, ISO, IMO, ICAO etc.). It may take decades to adjust all relevant international standards to take into account uses of alternative refrigerants. In particular, where respective safety, health and environmental risks are high, viable technical solutions are challenging, costs on the society are considerable and potential benefits are not clear.

V. Questions - Section B - Waste

Questions in relation to the use (mainly for industry associations)

The following linked information presents the current picture: Report summary waste july 2021.pdf

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In the tables presented on this page and the following, '?' in the cells show that the authorities do not have any information available. Input to fill these gaps is highly appreciated.

Sub-Use	Tonnage (tonnes/PFAS) per year in the EEA	Expected trend (--/-/0/+/++)[1]	Emissions/year in EEA[2] (tonnes/PFAS)
Textiles/TULAC	43,605	++	WWTP: 3.5 (median) Landfill: 1.8 (median) Incineration: Flue gas: ? Bottom ash: 0.03 Fly ash: 0.05
Food contact material (paper & board)	2,894	+	
End-of-life-vehicles (ELV)	2,219	+	
Waste electrical and electronic equipment (WEEE)	?	++	
Sewage sludge	0.404	?	0.3

[1] -- = strong decrease, - = decrease, + = increase, ++ = strong increase, 0 = neutral

[2] Emissions only relate to the waste stage. They do not include mixture/article production, mixture/article use and PFAS production. These emissions are covered in the other sections of this survey.

V. Questions - Section E - Waste

Specific questions for the use

Thank you for your participation!

This is the last page of the survey. Please make sure your information is correct. After clicking on 'Submit', you will not be able to change your entries anymore. The following page however will give you the opportunity to save your answers as PDF document or print them.

- Finish