AmCham EU
SPEAKING FOR AMERICAN BUSINESS IN EUROPE

Our position

Public consultation regarding the EU PFAS Restriction (Per- and polyfluoroalkyl substances (PFAS)

AmCham EU speaks for American companies committed to Europe on trade, investment and competitiveness issues. It aims to ensure a growth-orientated business and investment climate in Europe. AmCham EU facilitates the resolution of transatlantic issues that impact business and plays a role in creating better understanding of EU and US positions on business matters. Aggregate US investment in Europe totalled more than €3 trillion in 2020, directly supports more than 4.8 million jobs in Europe, and generates billions of euros annually in income, trade and research and development.

American Chamber of Commerce to the European Union
Speaking for American business in Europe

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The American Chamber of Commerce to the European Union brings together over 150 companies of US parentage committed to Europe on trade, investment and competitiveness issues. Aggregate US investment in Europe totalled more than €3 trillion in 2020, directly supports more than 4.8 million jobs in Europe, and generates billions of euros annually in income, trade and research and development.

AmCham EU has been an active stakeholder in REACH since its inception and remains committed to being a constructive partner in sharing industry insights with policy-makers to improve REACH and ensure that it effectively meets its objectives.

Our member companies include players across the whole value chain, from developers and producers, to downstream users and service providers. This allows us to represent the views of the entire value chain, bringing a diversified set of experiences to the table when it comes to uses, applications and alternatives to Per- and polyfluoroalkyl substances.

AmCham EU has been a key stakeholder throughout the recent REACH restriction process on Per- and polyfluoroalkyl substances. We have produced three position papers on the topic and we have participated in the first call for evidence launched by the authorities.

AmCham EU has submitted the online questionnaire providing information under the following sections:

- Medicinal products (both veterinary and human medicines);
- F-gas uses;
- Food contact materials;
- Electronics & energy.

With this document we wish to submit additional evidence and information that did not fit with the format and structure of the questionnaire.

We hope our input will provide useful information and ensure that the authorities have a complete overview of the role of PFAS in many key applications which, in some instances, contribute to the EU's objectives of climate neutrality and digital competitiveness.

We look forward to continuing our engagement and dialogue with the authorities around PFAS. Please do not hesitate to reach out to Emilie Bartolini (EBA@amchameu.eu) should you have questions regarding the content of our submission.

QUESTIONNAIRE

V. Questions - Section A - General questions

Are certain uses of PFAS missing in the categories above?

"Electronics & Energy"

In the category "Electronics & Energy", the following substances registered under REACH should be added for Data Centers – immersion cooling of semi devices/servers: CAS# 382-28-5, CAS# 338-83-0, CAS #1064698-37-8, CAS# 382-28-5, CAS# 375-03-1, CAS# 163702-08-7/163702-07-6 and CAS# 756-13-8.

- In the Electronics sector, fluoropolymers are used for wire and cable insulation due to their very low diaelectric constant, strength, flexibility, temperature stability, UV resistance, and low particulation. This allows cables that use fluoropolymers to achieve unmatched performance in highly demanding applications such as aerospace, test & measurement, clean room production, extreme environments and high speed data transmission.
- Additionally, in semiconductor manufacturing, fluoropolymer filters are used to process the aggressive chemicals needed to processes like chemical etching and photolithography.
- Fluoropolymers are also used as component in electronic devices beyond semiconductors themselves. They are used for thermal and electrical insulation gaskets.
- Fluoropolymer vents are used in a wide variety of electronic components ranging from computers, mobile phones and smart watches to telecommunications infrastructure such as base stations. Fluoropolymers are necessary to create durable, breathable barriers which prevent water entry and resist chemical, thermal and ultraviolet degradation.

In the use category "Electronics & Energy", the use of alternatives to sulfur hexafluoride (SF6) in Energy in electrical switchgear, gas insulated lines and other gas-insulated equipment is missing. It is important to note the use of fluorinated ketone (CAS # 756-12-7) and fluorinated nitrile (CAS # 42532-60-5) as alternatives to sulfur hexafluoride in this application.

- PTFE filters are used throughout the energy sector to improve performance and reduce environmental emissions. Turbine filters are used to improve the efficiency and reduce downtime of natural gas turbines. Mercury filters are used at coal based power plants to remove mercury from exhaust gases. PTFE filter bags, including some with catalytic functionality, are used to reduce particulate and chemical emissions from waste-to-energy plants.
- Fluoropolymers are used to enable electronic components used for oil & gas exploration such wire and capacitors for downhole well applications.

All of these applications require materials that can withstand harsh chemical and temperatures while remaining strong and air permeable.

In the use categories "F-gases", "Electronics & Energy" and "Transportation" the use of fluoroketone is missing as a clean agent fire suppression fluid (e.g. CAS # 756-13-8).

In the use category "Construction", the use of foam blowing additives in the production of energy efficient building material should be added (e.g. CAS #3709-71-5).

In the use category "Medical devices", the use of cooling liquids is mentioned, but the products with following CAS numbers are missing: CAS # 297730-93-9 and CAS # 1064698-37-8.

In the use category "F-gases", the electrical equipment application is mentioned, but the use of alternatives to sulfur hexafluoride (SF6) in electrical switchgear, gas insulated lines and other gas-insulated equipment is missing. It is important to note the use of fluorinated ketone (CAS # 756-12-7) and fluorinated nitrile (CAS # 42532-60-5) as alternatives to sulfur hexafluoride in this application.

It should be noted that there is an error in Appendix 1 in "Report summary F-gas uses". Entry 24 "methoxytridecafluoro-heptene isomers", MPHE Sion TM is NOT a fluoroketone.

Pharmaceutical Manufacturing

Use of PFAS in equipment and supplies used to manufacture pharmaceutical products. Processes to make pharmaceuticals require a high degree of cleanliness, purity, chemical stability and thermal resistance necessitating the use of fluoropolymers. They are commonly used in a variety of containers, tubing, filters and other processing equipment.

Chemical Production

Fluoropolymers in particular are used is a multitude of applications related to chemical manufacturing to seal equipment and containers to prevent the release of hazardous chemicals or for filtration applications to prevent air or water emissions during industrial processes. These sealant and filtration products are used during the manufacturing of many chemical and other materials, like acids, chlorine, carbon black, cement, TiO2, catalysts, mineral, polymers, fertilizers, pesticides, industrial & household cleaners, pulp & paper manufacturing and many others.

5. Transportation

- Fluoropolymers are necessary for additional applications in aerospace that require temperature and chemical resistance, thermal stability and high strength. Such applications include insulation for cables or gasket materials used in aircraft, spacecraft and satellites which are exposed to extreme conditions and require exceptional reliability.

- Many components and systems in automobiles require protective vents made from fluoropolymers. These vents are used to seal critical systems like headlamps, drive trains, or batteries from dirt, oils and water while allowing gases to pass through for safe, reliable performance.

6. Solid Waste Treatment

Fluoropolymers are used for the transformation of non-hazardous organic residues from households, industrial or agricultural generators into products which close the natural cycle to return valuable nutrients to soils contributing to soil health sustainably while supporting the carbon capture in the ground, addressing global challenges like climate change and food security.

Medicinal Products

Medicinal Products report summary: https://www.reach-clp-biozid-helpdesk.de/media/Helpdesk/download/Report%20summary%20medicinal%20products%20july%202021.pdf

Header (bold) / Question	Response Consolidated
V. Questions - Section B - Medicinal Products **Questions in relation to the use (mainly for industry associations)** **[table of sub-uses, volumes, emissions]**	
Do you have information that indicates that the information provided on the emissions should be adjusted? (yes/no)	Yes
Please specify and/or refer to literature/public sources. (1000 characters)	The volume of API is use will also be emitted; adjustment of the volume is proposed in the appropriate section. Intermediates are handled in closed controlled systems, with low emission to the environment. All waste streams are controlled. Intermediates under REACH are even manufactured under strictly controlled conditions, so no significant emission to the environment is permitted. The mentioned 10% release for intermediates are not plausible. This is far above the worst case default release factors used by ECHA for ERC1 (manufacture of intermediates; 6% to water) and ER6a (use of intermediates; 3% to water). Workplace exposure is limited by banding: https://www.cdc.gov/niosh/docket/review/docket290/pdfs/clean-cib-niosh-oebprocess-guidancefortheevaluationofchemicalhazards_3.8.17.pdf The life cycle of PFAS components used in production of any medicinal products (filters, membranes, surface lining etc, as provided by the Life Science industry) is well controlled.
Do you have information that indicates that the information provided on the tonnage should be adjusted? (yes/no)	Yes

Please specify and/or refer to literature/public sources. (1000 characters)	Pantoprazole as major contributor(about 250 t from 450 t in total) evades the new PFAS definition as it has a CF2H-moiety. Also applies to eflornithine, maraviroc, and roflumirast. On the other hand, certain PFAS API are missing: imported API are not registered under REACH, and some drug substance groups like anesthetics should be included here (see our comments in "Medical Devices"). An IQVIA query on PFAS medicines EU market volume are close to 1000 tons/a with a neutral trend, with inhalative anesthetics such as Sevoflurane (about 500 t/a) having much impact. They were filtered from the Top 200, so the actual figure may be somewhat higher. Registered intermediates were spot checked and some seem to be missing, as no PC code can be entered in the lifecycle description section. The actual volume is expected to exceed the given value. In general, the tonnages cannot be directly compared to other PFAS, as just a fraction of the rather large molecules is fluorinated.
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. (1000 characters)	No
Do you have information that indicates that the information provided on the expected trend should be adjusted? (yes/no)	Yes

Please specify and/or refer to literature/public sources. (1000 characters)	The observed marketing volume increase trend in Figure 2 of the report summary is only evident for Pantopazole, which needs to be removed to reflect the current PFAS definition. All other volumes are stagnant or slightly decreasing, and no clear trend can be observed.
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/no)	Yes
Please specify and/or refer to literature/public sources. (1000 characters)	Only a small number of API substances pose a risk to the environment, and they do not fall under the PFAS definition: https://www.sciencedirect.com/science/article/pii/S0160412019309493#f0005 Initiative between European healthcare, industry and student organisations on disposal: http://medsdisposal.eu/ Enrivonmental Risk Assessments are conducted prior to approval of all medicinal products. Recent and new draft EMA guideline: https://www.ema.europa.eu/en/environmental-risk-assessment-medicinal-products-human-use Technical justification for integrity of each individual manufacturing equipment and transport container exists (internal company documents)

V. Questions - Section C - Medicinal Products
Questions in relation to alternatives (mainly for individual companies)
[no table]

What is the specific application/functionality of PFAS in your product(s)/processes? (1000 characters)	Active pharmaceutical ingedients (API) and their production intermediates meet the PFAS definition even with a single perfluorated carbon atom. Selected fluorination modulates the binding affinity, absorption, stability and distribution in the body of the whole molecule. Fluorine is both small and has the highest electronegativity of all elements, making it an essential building block to develop safe and efficacious drugs. Additional PFAS are essential in pharmaceutical production. This applies to articles such as PTFE filters or machinery with surface treatment, but also to chemicals used in synthesis, for peptide coupling or as production aids. Examples are trifluoro acetic- acid or anhydride, nonaflates, trifluoro ethanol or the refrigerant R-134a. These chemicals and articles are not part of the product and their disposal is controlled.
Are in your view the listed non-PFAS alternatives technically feasible in your product(s)/processes? (yes/no)	No

Please specify why. 1000 characters	Due to the unique properties of fluorine, a direct replacement is not available. There are other electron withdrawing groups similar to -CF2- or -CF3 such as carboxylic esters, amides, nitro, or cyano, but they differ in stability, permeability, and toxicity. Example: Sorafenib (see Lowinger, T.B.; et al. Curr. Pharm. Des. 2002, 8, 2269-2278. Design and discovery of small molecules targeting raf-1 kinase). Here a CF3 group was key to achieve suitable in vivo activity. Sorafenib is currently used worldwide for treatment of liver, kindey and thyroid cancers. Other API with PFAS elements target serious autoimmune diseases including rheumatoid arthritis and infectious diseases including hepatitus C. The efficacy of the drugs is lost when the structure is changed. In production equipment, PFAS products are chosen based on their inert and non-stick properties. No alternatives are known without impacting the product quality.
Are in your view the listed non-PFAS alternatives economically feasible in your product(s)/processes? (yes/no)	No
Please specify why. 1000 characters	Drugs and API are developed for efficacy and safety. Any change of molecular structure delivers a different drug candidate. Consequently, there are no alternatives to the molecule, regardless of economic viewpoints. Production equipment is part of the validated process, so every change requires re-validation and thorough testing. This causes high qualification effort to evaluate non-PFAS alternatives, even in the unlikely case that such alternatives are found.
Do you have information on the alternatives' risk profile? (yes/no)	No
Please describe. 1000 characters	Not applicable (see above)
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/no)	Legal approval schemes for pharmaceuticals apply regardless of their structure (PFAS or not). Any potential alternative needs to go through EMA approvals and clinical phases, taking many years (according to Directive 2001/83/EC)
Please specify and/or refer to literature/public sources. (1000 characters)	Source: EFPIA "The Pharmaceutical Industry in Figures - Key Data 2021", p. 6
What is the average approval time? (1000 characters)	It takes about 10 years for research and development of new APIs. Registration and marketing authorisation have to be added to that time. https://www.researchgate.net/figure/Trends-in-drug-approval-timeThe-total-time-from-synthesis-of-a-compound-to-NDA_fig1_8568742
Do you actively work on finding alternatives? (yes/no)	No

Please specify. (1000 characters)	Fluorine is introduced in APIs when required due to stability/clearance, potency, pharmcokinetics, and/or bioavailability of the drug candidate when these cannot be adressed by other means. The introduction of fluorine is expensive and difficult from a synthetic chemistry point of view and can be considered a last resort within drug development.
If alternatives have been identified as potentially suitable, which timescale do you foresee for a complete transition to those? Please explain. (1000 characters)	Not applicable (see above)
Do you have information on additional alternatives for any of the described applications that have not been disclosed in the attached information? (1000 characters)	No

V. Questions - Section D - Medicinal Products
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 (1000 characters)	Prohibiting PFAS pharmaceuticals would remove multiple best-in-class medications from the EU market, although they are essential for public health and well-being. Affected therapeutic domains include, but are not limited to, cardiovascular & metabolic diseases, infectuous diseases, immunology, neuroscience, oncology and pulmonary hypertension. The resulting loss of therapeutic options and access to medication prevails over financial or job-related concerns. Prohibiting PFAS manufacturing materials, which are not part of the end product, would move production of numerous drugs and vaccines to non-EU countries, along with the jobs in production.
b) in 10 years (1000 characters)	Same as above.
c) Please explain by providing your calculations. (1000 characters)	The social impact of poorer healthcare is measurable when pharmaceuticals are lost to the patients, and when no equally suitable alternatives are available. Unlike the economic impact this cannot be mitigated.

What is the economic impact (euro) on your business/company, if the following measures will become mandatory? Please make your (indicative) calculations transparent.	Any medicinal product containing more than 0.1 % PFAS APIs, which are required to be efficient, such a threshold would mean to phase out these products (with no replacement)
a) A maximum concentration of e.g. 0.1% (or less) PFAS is set in mixtures and/or articles. (1000 characters)	
b) Obligation to label your products visibly with "Contains PFAS". (1000 characters)	Minimal impact if in leaflet. Should be a position which is not already occupied by other important information to the patient on the use of the medicinal product. May raise concerns by patients leading to the medication not being taken, although the labeling is not safety related. Moreover, the benefit of the labeling is unclear, when compared to e.g. clear disposal advice.
c) Obligation to report amount of PFAS in use and respective emissions. (1000 characters)	Moderate impact, depending on bureaucratic burden. If introduced, a minimal reporting threshold is suggested.
d) Specific waste management requirements with the obligation to collect, treat or recycle PFAS containing waste separately. (1000 characters)	Impossible for used medicinal product, as emitted through patient. Impact of waste water emissions is subject to EMA environmental impact analysis and to the Pharmaceuticals in the Environment (PIE) initiative. Additionally, in case of use in hospitals specific waste management schemes are in place. For unused product, initiatives to reduce waste emissions are already established: http://medsdisposal.eu/ For production equipment (filters, machinery), impact is low, as waste streams are already controlled by the manufacturing company.
e) In case you are using PFAS polymers: no PFAS processing aids are allowed during polymer production. (1000 characters)	not applicable

V. Questions - Section E - Medicinal Products

Specific questions for the use

If available, please provide information that allows a quantitative estimation of tonnages of PFAS veterinary medicines and a trend in these tonnages. (1000 characters)	not applicable
If available, please provide information on alternatives for (main) PFAS veterinary medicines. (1000 characters)	not applicable

If available, please provide information on the EEA dependency on pharmaceutical import. (1000 characters)

If available, please provide information on PFAS emissions during pharmaceutical production. (1000 characters)	No significant emission of any PFAS happens during manufacturing of pharmaceutical substances or finished pharmaceuticals. All waste streams are collected and disposed of according to regulations. Emissions via air (off-air treatment), wastewater or soil are strictly controlled under REACH. The Eco-Pharmaco-Stewardship (EPS) is an important holistic initiative to address emerging environmental concerns: https://www.efpia.eu/news-events/the-efpia-view/efpia-news/151009-eco-pharmaco-stewardship-eps-a-holistic-environmental-risk-management-program/

V. Questions - Section B - Medicinal Products

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

Q1: Do you have information that indicates that the information provided on the tonnage should be adjusted?

NO

Q2: Do you have information that indicates that the information provided on the emissions should be adjusted?

Only a small number of API substances pose a risk to the environment, and they do not fall under the PFAS definition: https://www.sciencedirect.com/science/article/pii/S0160412019309493#f0005
Initiative between European healthcare, industry and student organisations on disposal: http://medsdisposal.eu/
Enrivonmental Risk Assessments are conducted prior to approval of all medicinal products. Recent and new draft EMA guideline: https://www.ema.europa.eu/en/environmental-risk-assessment-medicinal-products-human-use
Technical justification for integrity of each individual manufacturing equipment and transport container exists (internal company documents)

NO

Q3: 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 (Max 1000 characters).

An Environmental Risk Assessment is systematically performed on any Veterinary Medicinal Product (VMP) before a marketing authorisation is granted. An exposure assessment is performed on the use phase of the product, resulting in predicted environmental concentrations PECs for (the) substance(s) used in the medicine. To determine potential risk, the PEC/PNEC risk quotient methodology is used. The ERC is not applicable to medicines.

Q4: Do you have information that indicates that the information provided on the expected trend should be adjusted?

NO

Please specify and/or refer to literature/public sources (max 1000 characters)

Not applicable, since ERC are not determined.

Q5: 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 (max 1000 characters)

For Veterinary Medicinal Products (VMPs) any authorized product has gone through a full review of quality, efficacy and safety. This includes target animal safety, user safety, public safety and environmental safety. If necessary, risk management is proposed and warning statements/use restrictions are added to the product label and leaflet. All VMPs containing PFAS are only delivered to animal patient under prescription, therefore the use is regulated and driven by health needs.

V. Questions - Section C - Medicinal Products and Medical Devices
Questions in relation to alternatives (mainly for individual companies)

Q1: What is the specific application/functionality of PFAS in your product(s)/processes?

Maximum 1000 characters

For VMPs, the active pharmaceutical ingredients (APIs) qualifying as PFAS are responsible for the therapeutic effects.

Q2: Are in your view non-PFAS alternatives technically feasible in your product(s)/processes?

NO

Please specify why (maximum 1000 characters)

No; an API defines the product. Using a different API results in a different VMP. PFAS used in synthesis are typically not replaceable.

Q3: Are in your view non-PFAS alternatives economically feasible in your product(s)/processes?

NO

Please specify why (maximum 1000 characters)

No, as the product would need to be abandoned as a whole.

Q4: Do you have information on the alternatives' risk profile?

YES/NO

Please describe (maximum 1000 characters)

This is not really applicable. An alternative would need to be a different product with a different API but with ultimately the same therapeutic effect. Such alternatives are not readily available and for some therapeutic areas, may be very difficult to find. So we don't have information on alternatives.

Q5: 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/NO

Please specify and/or refer to literature/public sources (maximum 1000 characters)

Yes. Directive 2001/82/EC, to be replaced by Regulation 2019/6 in January 2022; and Regulation 470/2009. The requirements regarding safety (see Annex II of the Directive and Regulation 470/2009) are similar or even more stringent than those from REACH. In addition, data requirements are the same for all VMPs and are independent of volumes or tonnage levels. Decisions to authorise products on the market are made based on the benefit-risk balance of the product: if the therapeutic benefits outweigh the risks the product will be approved.

Q6: What is the average approval time? (Maximum 1000 characters)

Development phase ranges between 10 and 15 years followed by an approval procedure requiring 1.5 to 2 years.

Q7: Do you actively work on finding alternatives?

YES/NO

Please specify (maximum 1000 characters)

The veterinary pharmaceuticals industry is continuously working on the development of new/better therapeutic VMPs to treat diseases and conditions in the variety of animal species presented in veterinary medicine. Actually, some of the APIs qualifying now as PFAS fill important treatment gaps where either no VMP was available, or where the efficacy of older alternatives is incomplete or insufficient to deal with therapeutic needs. In that respect, our industry is continuously working on alternatives, but in view of the long development and approval times, if PFAS-containing medicines are banned there will not be any suitable alternative VMPs for a long period of time, sometimes decades. Simple substitution with an alternative is not possible.

Q8: If alternatives have been identified as potentially suitable, which timescale do you foresee for a complete transition to those? Please explain (Maximum 1000 characters)

Q9: Do you have information on alternatives for any of the described applications in the attached information?

Almost 2 decades, sometimes longer as explained above depending on if alternatives for a certain therapeutic indication could be found a priori.
No, we are not aware of any readily available alternatives. Also, the attached information is incomplete (e.g. inhalation anaesthetics isoflurane, sevoflurane: all others are also PFAS but not listed here; complex surgery would no longer be possible).

(Maximum 1000 characters)

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

Q1: 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 (max 1000 characters)

– Societal impacts reach further than just direct and indirect jobs in the sector. Therapeutic gaps, profound impact on animal heath, increased suffering and death, risks to public health as some of these conditions also affect humans if the animals are not treated. – Job losses in commercial departments, R&D and manufacturing. In case of international companies, manufacturing currently based in the EU for the rest of the world would need to move out of the EU. Loss of products would mean loss of jobs in production lines for these products. – Implications for wholesalers, pharmacies and veterinary clinics.

b) In 10 years (max 1000 characters)

c) Please explain by providing your calculations (max 1000 characters)

Q2: 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 (max 1000 characters)

The dose is determined by efficacy parameters and a 0.1% limit for the active substance is impossible. This effectively equals a ban.

Same as above, as impact lasts for more than 10 years, potentially decades.

b) Obligation to label your products visibly with "Contains PFAS" (max 1000 characters)

PFAS is a chemical group; the fact that a substance qualifies as a PFAS doesn't mean that it is harmful by default. See:

Herzler et al (2021). The "EU chemicals strategy for sustainability" questions regulatory toxicology as we know it: is it all rooted in sound scientific evidence? Archives of Toxicology 95:2589–2601. https://doi.org/10.1007/s00204-021-03091-3

Barile et al (2021). The EU chemicals strategy for sustainability: in support of the BfR position. Archives of Toxicology 95:3133–3136. https://doi.org/10.1007/s00204-021-03125-w

VMP regulations require clear and targeted warning statements for every risk that is identified during the approval process, including environmental risks. Instructions for proper disposal are also included. "Contains PFAS" is not meaningful in that context.

Under VMP legislation, such statement wouldn't be allowed as labelling of VMPs is strictly regulated.

c) Obligation to report amount of PFAS in use and respective emissions (max 1000 characters).

This raises a high bureaucratic burden for the pharmaceutical sector without any benefit to the animal patient, public health or the environment. In addition, "emissions" by means of animals potentially excreting substance are impossible to quantify.

d) Specific waste management requirements with the obligation to collect, treat or recycle PFAS containing waste separately (max 1000 characters).

Product labels already contain instructions for disposal. Manufacturing processes are strictly controlled and in most cases, waste streams from production are incinerated. PFAS intermediates are mostly fully consumed during production leaving no waste.

e) In case you are using PFAS polymers: no PFAS processing aids are allowed during polymer production (max 1000 characters).

No PFAS polymers are used in VMPs.

V. Questions - Section E - Medicinal Products Specific questions for the use

Q1: If available, please provide information that allows a quantitative estimation of tonnages of PFAS veterinary medicines and a trend in these tonnages (max 1000 characters).

Usage is expected to remain stable relative to the European animal population, any increase or decrease would follow an increase or decrease in animal population.

Q2: If available, please provide information on alternatives for (main) PFAS veterinary medicines (max 1000 characters).

As stated before, there are no alternatives.

Q3: If available, please provide information on the EEA dependency on pharmaceutical import (max 1000 characters).

Important global manufacturing capacity is located within the EEA. Actions on PFAS will drive this out of the EEA to other regions of the world.

Q4: If available, please provide information on PFAS emissions during pharmaceutical production (max 1000 characters).

This is very product- and company-specific and general information cannot be given. However, as stated above, manufacturing is strictly controlled, with relevant waste streams usually destroyed, therefore, emissions are minimal.

F-GASES

V. Questions - Section B - F-gas uses - Questions in relation to the use (mainly for industry associations)

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.

Reduction in F-gas use in commercial refrigeration due to bans in EU F-gas regulation

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

Yes

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

Emission reduction to the environment in HVAC-R sector - by record keeping, leak test, maintenance, labelling, worker qualification and recovery and recycling mandatory obligations as set out in the EU F-gas regulation.

In fire protection applications, the fluoroketone fire suppression agent (CAS #756-13-8 with GWP<1) is stored as a liquid and discharged as a gas. This product is used in a closed system. The fluid remains in place unless there is a fire event and discharge. If a fire suppression system is decommissioned, the fluid can be collected, recycled, and reused.

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

As a refrigerant in HVAC-R equipment.

In fire protection applications, the fluoroketone fire suppression agent (CAS #756-13-8 with GWP<1) is used to suppress fires in enclosures that house high-value electronics or other assets that would be damaged by water sprinkler suppression systems. Common applications include electrical control rooms or underground substations, data centers, telecommunications switch rooms, computer control rooms, airport control towers, clean rooms, and computer-controlled manufacturing operations as well as in archives and museums with paper archives, historical documents, priceless works of art and antiquities where other fire protection fluids cannot be used. The fluoroketone fire suppression systems are also used in marine vessels. This material is a replacement for ozone depleting substances and compounds with high global warming potential (GWP) including halons and hydrofluorocarbons (HFCs). This product is a very low GWP (<1.0) clean extinguishing fire protection fluid.

In building materials, a PFAS-based foam additive (CAS# 3709-71-5) is used as a foam insulation additive due to its effectiveness in reducing the foam cell size and thus the thermal conductivity of polyurethane and other rigid foam formulations. It is used in the production of rigid insulation polyurethane foam products to meet the latest EU thermal conductivity specifications (e.g., DIN EN 13165). Typical usage rate for this product is as low as 0.5% of the total foam weight and this product is used in a closed manufacturing process. The foam additive is incorporated into the final foam product.

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

No

Please specify why.

If technically feasible, ie comply with 5 main criteria - economic, safety, energy efficiency, environment and sustainability (ease of manufacture) none of alternatives present a technically feasible alternative for all HVAC applications. Similar situation in commercial refrigeration, although CO2 and propane can cover a lot of

applications. Alternatives further limited in transport refrigeration due to mobile nature and attendant safety concerns (use in ferries, tunnels etc) environment and sustainability (ease of manufacture) none of alternatives present a technically feasible alternative for all HVAC applications. Similar situation in commercial refrigeration, although CO2 and propane can cover a lot of applications. Alternatives further limited in transport refrigeration due to mobile nature and attendant safety concerns (use in ferries, tunnels etc).

For fire protection agents, non-PFAS fire protection agents include water, carbon dioxide, dry chemical, and inert gases. These non-PFAS fire protection agents can cause corrosion, can damage equipment or valuable artifacts, can be electrically conductive, are slower drying, can leave a residue, may have higher toxicity, may require high operating pressures, and may result in higher maintenance costs. In the case of carbon dioxide systems, there are reported cases of safety incidents. The link to one such incident is here: koreaherald.com/view.php?ud=20180904000834. In the case of inert gas systems, there are extra costs required to make an inert gas system safe, including extra ventilation, extra structural strength to support the weight of the system, and more expensive testing and checkout costs. The fluoroketone fire suppression agent with CAS #756-13-8 has the highest margin of safety for human occupancy among clean agents, including inert gas.

For the PFAS-based foam additive (CAS# 3709-71-5) we are not aware that any non-PFAS direct alternatives exist. Elimination of the additive will reduce overall performance of the foam insulation by increasing thermal conductivity and thus lowering energy efficiency of the polyurethane foam insulation. The use of the additive in addition to the foam blowing agent makes it possible to meet the latest EU thermal conductivity specifications (e.g., DIN EN 13165).

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

No

Please specify why.

If alternatives would be economically feasible they would already be widely available, eg propane in domestic refrigeration and CO2 in commercial refrigeration. Providing an answer would require a breakdown in specific sub-sectors given the wide range of applications.

Non-PFAS alternatives are not economically feasible in HVAC and transport apart from some niche applications.

In the case of non-PFAS fire protection agents, the inert gases, they take up more room and that additional needed space has cost implications. The inert gases also need to displace more air to put out a fire, so more cylinders of gas are needed and thus would results in additional costs in the event of recharge. There are also reported incidents of inert gas fire suppression systems causing damage to IT hardware. The link to one such incident is here and includes references to other such events: datacenterdynamics.com/en/news/air-conditioning-fire-suppression-took-down-australian-betting-site-tabcorp/. There are also extra costs required to make an inert gas system safe, including extra ventilation, extra structural strength to support the weight of the system, and more expensive testing and checkout costs.

Do you have information on the alternatives' risk profile?

Yes

Please describe.

Standard part of refrigerant assessment is an assessment of the risk profile during the development phase of any of our products.

In the case of fire suppression, the fluoroketone fire suppression agent with CAS #756-13-8 has the highest margin of safety for human occupancy among clean agents, including inert gas. As referenced before, in the case of carbon dioxide systems, there are reported cases of safety incidents. There are also reported incidents of inert gas fire suppression systems causing damage to IT hardware.

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..

Main legal drivers have been compliance with the Montreal Protocol and the EU F-gas. Compliance also with safety standards of products and compliance with safety and building codes when installed or used. Mainly national and local building codes, EU standards (e.g. EN378) and regulations (e.g. machinery, pressurised equipment (PED) and ATEX directives) and UN/ECE and ATP codes for transport refrigeration.

In case of the PFAS-based foam additive (CAS# 3709-71-5), elimination of the additive will reduce the overall performance of the foam insulation by increasing thermal conductivity and thus lowering efficiency of the polyurethane foam insulation, which could prevent the providers of building materials from meeting the latest EU thermal conductivity specifications (e.g., DIN EN 13165).

What is the average approval time?

Legal compliance only (not including time for R&D and development) and depending on legal framework for specific sectors, vary from 3 and 5 years depending on notifying body and compliance (public safety) authorities.

Do you actively work on finding alternatives?

Yes

Please specify.

Some AmCham EU members were the first to move out of using ozone depleting substances and pioneers in developing and using low global-warming solutions across several different applications (HVAC, refrigerants, fire suppression systems, etc.). Compliance with the EU F-gas regulation and the existing safety standards is driving our choices and the choices of our customers.

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

Typical development cycle for HVAC-R products is 3-5 years. New processes, materials, testing and re-tooling need to be carried out.

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

Potentially there are not-in-kind alternatives using no refrigerants, but they are still at theoretical stage.

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.

Severe negative impact on manufacturing and exports and competitiveness of European operations. Existing product ranges using PFAS become obsolete. No practicable time to develop and acquire certification of new product ranges. Knock on consequences of loss of competitiveness would undermine business case for many operations in Europe. Additional social impact would be the non-availability of HVAC-R products in many applications and the impossibility to use alternatives due to legal, regulatory and safety constraints.

b) In 10 years.

Still significant impact, but more time to theoretically develop and market alternatives. Unlikely to be able to provide alternatives across HVAC, heat pump and commercial refrigeration ranges. Legal, regulatory and safety constraints (which we have no control over) would remain. Please note that a single date has not been considered as practical in refrigerant legislation for Ozone Depleting Substances (ODS) - they have clear time limits applying to new equipment, exports and imports and installed equipment to avoid economic dislocations.

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 gas concentration limit by weight does not make sense for HVAC and refrigeration equipment that are often empty (non-charged) when put on the market. If only applied to gas containers, this would mean that all existing equipment would not be able to be serviced and maintained. For this reason, legislation for Ozone Depleting Substances (ODS) have clear time limits applying to new equipment, exports and imports and installed equipment to avoid economic dislocation Legal obligations (e.g. obligation to notify imports and labelling requirements) determined by weight would not be appropriate for putting on the market or exporting HVAC-R products.

A maximum mixture and/or article concentration such as 0.1% or less is not relevant to the fluorochemical fluids. They are typically used at 100% concentration in the F-Gas Uses applications described. High PFAS concentrations of these products referenced may be needed for the required performance in typical applications. They are used at 100% concentration when used as fire protection fluids.

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

Warning Labelling is already an obligation under the EU F-gas regulation. We would support clear labelling for users and workers maintaining and servicing HVAC-R equipment to warn them against any emissions/leakage from equipment.

The definition of PFAS defined by the competent authorities under REACH is a very broad definition that encompasses not only non-polymeric but also polymeric PFAS. Trying to restrict PFAS as one group of +/- 4,700 substances with different chemical structures (e.g., polymeric versus non-polymeric, perfluorinated versus polyfluorinated, reactive versus non-reactive etc.) and physicochemical properties (e.g., gas versus liquids versus solid, hazardous versus non-hazardous, etc.) is not scientifically appropriate. Across this vast group of

substances there is a large variation in the properties of persistence, bioaccumulation, mobility and toxicity. A general label such as "contains PFAS" inadvertently implies that this vast group of substances is similar in properties and could mislead the users of these substances.

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

Obligations are already in place under the EU F-gas regulation for gathering and reporting F-gas use in stationary HVAC-R and refrigerated transport use. For SMEs the reporting of PFAS use and estimated emissions could be considered burdensome in terms of the costs and manpower required for the reporting. This will depend on the scope and complexity of the requirements. A thorough analysis of what substances of the vast population of PFAS, which is more than 4,700 substances per the currently used definition, warrant such reporting due to factors such as level of toxicity, should be undertaken.

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

Recovery and recycling obligations are already set out in the EU F-gas regulation.

In many applications for the fluorochemical fluids, the fluids are used in closed systems and in systems in which the fluids are recycled in-situ to maximize their useful life and to maximize the total cost of ownership / return on investment. It is also possible to collect emissions during the processing for re-use.

V. Questions - Section E - F-gas uses

Specific questions for the use

Within the following applications/uses, what are the barriers to the substitution from F-gases to fluorine-free alternatives, and how much time would it require to address those?

Barriers to substitution.

Commercial refrigeration, and specially alternatives to F-gases in mid to large scale facilities	Legal phase out requirement under F-gas regulation regarding refrigeration already in place. For mid to largescale facilities safety concerns do not allow for alternatives
Transport refrigeration	Safety concerns and regulations, eg to travel through tunnels, ferries etc within and outside EU
Mobile air conditioning in cars, vansand trucks	n/a
Foam Blowing Agent, both closed and open cell	n/a

Commercial refrigeration, and specially alternatives to F-gases in mid to large scale facilities	Safety regulations not under our control
Transport refrigeration	Safety regulations not under our control
Mobile air conditioning in cars, vans and trucks	n/a
Foam Blowing Agent, both closed and open cell	n/a

Time required to address barriers to substitution.

Is there any potential niches, systems or processes that would still rely on F-gas use in a10-years perspective within the applications/uses mentioned above, but also in other ones, such as for example:

Reliance on F-gases in a 10-year perspective?

Industrial refrigeration	Yes
Domestic air conditioning and heat pumps for space heating	Yes
Commercial air conditioning and heat pumps	Yes
Solvents	Yes
Propellants (non-MDI)	No answers
Electronic cooling	Yes
Other (please specify in the field to the right)	Dielectric insulating gases, fire suppression equipment, foam blowing agents, data center cooling

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? Yes

Data Center Cooling:

Though liquids at room temperature and thus not meeting the definition of F-Gas provided, some of the fluorochemical heat transfer fluids are included in Annex 1 of the EU F-Gas regulation (i.e., CAS #1064697-81-9) and Annex 2 of the EU F-Gas regulation (i.e., CAS# 375-03-1, CAS # 163702-08-7/163702-07-6 & CAS # 163702-06-5/163702-05-4). Fluorochemical heat transfer fluids can be used for liquid immersion cooling applications in data centers. Immersion cooling is a method for cooling data center IT hardware by directly immersing the hardware in a non-conductive liquid. Heat generated by the electronic components is directly and efficiently transferred to the fluid. This reduces the need for interface materials, heat sinks, fans, shrouds, sheet metal and other components that are common in traditional cooling methods. Immersion cooling with these fluids offers many benefits compared to traditional air cooling, including increased thermal efficiency (i.e., lower power usage effectiveness or PUE) and increased performance and reliability of data centers. Immersion cooling also eliminates the need for complex airflow management. Optimized immersion-cooled data centers can lead to reductions in capital and operating expenses, as well as a reduction in construction time and complexity. The increased compute density from immersion cooling allows for more flexible data center layouts and removes barriers to data center location choices such as areas with high real estate costs or space limitations. Finally, immersion cooling with these fluids can help eliminate the tradeoff between water usage, energy efficiency and cost by eliminating the need for chillers with economizers and complex controls used in air cooling. This helps eliminate the use of water needed to cool the data center by, instead, utilizing natural water temperatures in many climates to allow for full capacity cooling without evaporation infrastructure.

Dielectric Insulating Gases:

PFAS-based insulating gases (CAS# 42532-60-5 and CAS# 756-12-7) are used in gas mixtures in medium-voltage and high-voltage gas insulated power generation and distribution equipment including gas insulated switchgear and gas insulated lines in place of sulfur hexafluoride, a potent greenhouse gas with GWP of 23,500. Existing installations using gas mixtures with these insulating

gases are demonstrating the potential to reduce greenhouse gas emissions by more than 99% compared to installations using SF_6. Non-PFAS electrical insulation includes vacuum, interrupter/air-based technology. However, it is unlikely that the full voltage range can be covered by this technology. Furthermore, the increased space requirements of this technology when used in high voltage applications results in an overall worse life cycle management assessment compared to equipment using the mentioned insulating gas mixtures.

ELECTRONICS AND ENERGY

V. Questions - Section B - Electronics & energy

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

For the applications of the fluorochemical fluids in Electronics and Energy, including solvent cleaning, carrier solvent, heat transfer, thermal testing, coating, fire suppression, data center electronics immersion cooling and insulating gases, it is possible that these products can be emitted to the air during use. However, these products are typically used in closed systems in which users manage and minimize emissions or in systems in which the fluid and vapor can be captured, collected, recycled, and re-used. The products can be filtered in-situ to extend useful life and can be recycled and reused.

Regarding the electronics cooling applications for data centers, the following comments are provided regarding “Report summary Electronics and Energy”, Section 7, “Emissions”: The text provided comments: “Currently a yearly loss of immersion cooling liquid in 2 phase systems of 1% is said to be industry best practice.” We agree this may represent current practices, however, with the desire to reduce cost and emissions, practices will be improved. It is reasonable to believe that the industry will achieve evaporative losses on the order of 0.1% per year from ongoing improvements to both tank design and operational controls (i.e., operating procedures to perform routine maintenance). Additionally, due to the anticipated increased reliability of hardware used in immersion cooling, one reference mentions a fail-in-place concept where maintenance would be delayed which could further reduce fluid loss. See the following reference: (news.microsoft.com/innovation-stories/datacenter-liquid-cooling/). This could reduce emissions to an even lower threshold.

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

The fluorochemical heat transfer fluids are used for liquid immersion cooling applications in data centers. Heat generated by the electronic components is directly and efficiently transferred to the fluid. This reduces the need for interface materials, heat sinks, fans, shrouds, sheet metal and other components that are common in traditional cooling methods. Immersion cooling offers many benefits compared to traditional air cooling, including increased thermal efficiency (i.e., lower power usage effectiveness or PUE) which results in increased performance and reliability of data centers. Immersion cooling also eliminates the need for complex airflow management. Optimized immersion-cooled data centers can lead to reductions in capital and operating expenses, as well as a reduction in construction time and complexity. The increased compute density from immersion cooling allows for more flexible data center layouts and removes barriers to data center location choices such as areas with high real estate costs or space limitations. Finally, immersion cooling can help eliminate the tradeoff between water usage, energy efficiency and cost by eliminating the need for chillers with economizers and complex controls used in air cooling. This helps eliminate the use of water needed to

cool the data center by, instead, utilizing natural water temperatures in many climates to allow for full capacity cooling without evaporation infrastructure.

Section C. Are in your view the listed non-PFAS alternatives technically feasible in your product(s)/processes? NO.

There is no substitution in the applicable use areas described for the fluorochemical fluids used in Electronics and Energy with equally high performing, technically and economically feasible products. The chemistries of the PFAS substances are key to achieve the required high performance and durability of the products in the various use areas. Any non-PFAS substance used in these applications is expected to exhibit inferior performance, and a detailed and comprehensive life cycle assessment would still need to demonstrate whether the various uses would result in a lower potential impact on the environment. Otherwise, there is substantial risk of making a non-science based and ultimately regrettable substitution. Many of these high performance and highly durable products, used in a critical environment from a health and safety point of view, have to be qualified and/or certified, which means that any different product developed, if at all possible and advisable, would need to go through a lengthy qualification process.

For immersion cooling of electronics in data centers, non-PFAS heat transfer fluids include mineral oils, synthetic oils and natural oils. These materials are prone to dissolving hydrocarbon-based polymers and are therefore less likely to be compatible with adhesives, elastomers, and thermal interface materials. Moreover, most hydrocarbons are combustible and/or flammable. Therefore, hydrocarbons may pose an unacceptable risk to safety and infrastructure for many applications, particularly in two-phase immersion cooling. Hydrocarbon fluids with sufficiently high boiling points and flash points can be used in some single-phase applications, but they have the disadvantage of being relatively viscous (especially at low temperature) and do not evaporate readily from hardware when it is removed for service creating maintenance issues.

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

Why?

Often non-PFAS alternatives to the fluorinated liquids can cost as much as 10X or more versus non-fluorine containing materials. Industry is only willing to pay this premium in challenging applications where the unique attributes of the fluorinated materials are necessary. Otherwise, industry will generally use the most cost-effective solution that meets the needs of the application. In the industries in which these products are used (e.g., semiconductor, automotive, electronics, energy, healthcare, and government), the costs and timeline for research, development, testing, qualifications, and changes to processes would be significant even if suitable alternatives could be identified. Any changes would have to be evaluated to understand if more complex environmental, health and safety challenges would be created, and the increased costs would be passed downstream to customers.

In the case of immersion cooling of electronics in data centers, a more holistic view of the true value and cost of immersion cooling should consider cost on the scale of an entire datacenter, including annual savings for water and energy. Datacenters built for immersion cooling can be built in less time, require a smaller footprint, use less water and less energy to provide equal or greater computing power compared to an air cooled datacenter. The non-PFAS fluids, including mineral oils, synthetic oils and natural oils, would not be expected to have this same advantage due to the higher propensity to become contaminated and lower stability and lifetime expectations.

Section C. Do you have information on the alternatives' risk profile?

In the case of non-PFAS fluids used in immersion cooling, these fluids may be flammable and/or combustible.

Section D. 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 mixture and/or article concentration such as 0.1% or less is not relevant to the fluorochemical fluids. They are used at 100% concentration of PFAS as heat transfer fluids, including when used in electronics cooling in data centers.

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

The definition of PFAS defined by the competent authorities under REACH is a very broad definition that encompasses not only non-polymeric but also polymeric PFAS. Trying to restrict PFAS as one group of +/- 4,700 substances with different chemical structures (e.g., polymeric versus non-polymeric, perfluorinated versus polyfluorinated, reactive versus non-reactive etc.) and physicochemical properties (e.g., gas versus liquids versus solid, hazardous versus non-hazardous, etc.) is not scientifically appropriate. Across this vast group of substances there is a large variation in the properties of persistence, bioaccumulation, mobility and toxicity. A general label such as "contains PFAS" inadvertently implies that this vast group of substances is similar in properties and could mislead the users of these substances.

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

Manufacturers are reporting production of F-Gases today and reporting manufacturing emissions. If the reporting procedures are reasonable in terms of scope and detail, it can be feasible for manufacturers to report on a broader basis. However, it should be recognized that such details can be considered confidential business information.

For users of PFAS, who may be small companies, the reporting of PFAS use and estimated emissions could be considered burdensome in terms of the costs and manpower required for the reporting. This will depend on the scope and complexity of the requirements. This reporting requirement should be fully studied before implementation. A thorough analysis of what substances of the vast population of PFAS, which is more than 4,700 substances per the currently used definition, warrant such reporting due to factors such as level of toxicity, should be undertaken.

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

In many applications the fluorochemical heat transfer fluids are used in closed systems and in systems in which the fluids are recycled in-situ to maximize their useful life and to maximize the total cost of ownership / return on investment. It is also possible to collect emissions during the processing for re-use.

There are companies in the EU/UK who collect used fluids and re-process them to be resold. In a large scale manufacturing facility where the fluids are initially produced it is feasible to receive and re-process larger amounts of used fluids.

FOOD CONTACT MATERIALS

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

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?

The EU plastics manufacturing Industry may potentially be impacted by the proposed restriction, both in terms our manufacturing facilities and product formulation.

Due to the potentially very broad scope of the proposed PFAS restriction, the final impact is extremely difficult to estimate at this time.

However, the Plastic Industry in the EU employs over 1.5 million people, has a turnover of EUR 350 billion, and contributes close to EUR 30 billion per annum . If the proposed restriction impacts the functionality of sites or product formulation in a way which cannot be effectively mitigated, then a knock-on impact to employment, investment and the socio-economic contribution of the industry could reasonably be anticipated.

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

The EU plastics manufacturing Industry may potentially be impacted by the proposed restriction, both in terms our manufacturing facilities and product formulation.

Due to the potentially very broad scope of the proposed PFAS restriction, the final impact is extremely difficult to estimate at this time.

However, the Plastic Industry in the EU employs over 1.5 million people, has a turnover of EUR 350 billion, and contributes close to EUR 30 billion per annum . If the proposed restriction impacts the functionality of sites or product formulation in a way which cannot be effectively mitigated, then a knock-on impact to employment, investment and the socio-economic contribution of the industry could reasonably be anticipated.

V. Questions - Section A - General questions

Are certain uses of PFAS missing in the categories above? Please see below a list of missing uses per category. Some of the categories are not included in the questionnaire.

"Electronics & Energy"

- In the category "Electronics & Energy", the following substances registered under REACH should be added for Data Centers – immersion cooling of semi devices/servers: CAS# 382-28-5, CAS# 338-83-0, CAS #1064698-37-8, CAS# 382-28-5, CAS# 375-03-1, CAS# 163702-08-7/163702-07-6 and CAS# 756-13-8.
- In the Electronics sector, fluoropolymers are used for wire and cable insulation due to their very low diaelectric constant, strength, flexibility, temperature stability, UV resistance, and low particulation. This allows cables that use fluoropolymers to achieve unmatched performance in highly demanding applications such as aerospace, test & measurement, clean room production, extreme environments and high speed data transmission.
  - Additionally, in semiconductor manufacturing, fluoropolymer filters are used to process the aggressive chemicals needed to processes like chemical etching and photolithography.
  - Fluoropolymers are also used as component in electronic devices beyond semiconductors themselves. They are used for thermal and electrical insulation gaskets.
  - Fluoropolymer vents are used in a wide variety of electronic components ranging from computers, mobile phones and smart watches to telecommunications infrastructure such as base stations. Fluoropolymers are necessary to create durable, breathable barriers which prevent water entry and resist chemical, thermal and ultraviolet degradation.
- In the use category "Electronics & Energy", the use of alternatives to sulfur hexafluoride (SF6) in Energy in electrical switchgear, gas insulated lines and other gas-insulated equipment is missing. It is important to note the use of fluorinated ketone (CAS # 756-12-7) and fluorinated nitrile (CAS # 42532-60-5) as alternatives to sulfur hexafluoride in this application.
- PTFE filters are used throughout the energy sector to improve performance and reduce environmental emissions. Turbine filters are used to improve the efficiency and reduce downtime of natural gas turbines. Mercury filters are used at coal based power plants to remove mercury from exhaust gases. PTFE filter bags, including some with catalytic functionality, are used to reduce particulate and chemical emissions from waste-to-energy plants.
- Fluoropolymers are used to enable electronic components used for oil & gas exploration such wire and capacitors for downhole well applications.

All of these applications require materials that can withstand harsh chemical and temperatures while remaining strong and air permeable.

F-gases

- In the use categories "F-gases", "Electronics & Energy" and "Transportation" the use of fluoroketone is missing as a clean agent fire suppression fluid (e.g. CAS # 756-13-8).
- Furthermore the electrical equipment application is mentioned, but the use of alternatives to sulfur hexafluoride (SF6) in electrical switchgear, gas insulated lines and other gas-insulated equipment is missing. It is important to note the use of fluorinated ketone (CAS # 756-12-7) and fluorinated nitrile (CAS # 42532-60-5) as alternatives to sulfur hexafluoride in this application.

Construction

In the use category "Construction", the use of foam blowing additives in the production of energy efficient building material should be added (e.g. CAS #3709-71-5).

Medical devices

In the use category "Medical devices", the use of cooling liquids is mentioned, but the products with following CAS numbers are missing: CAS # 297730-93-9 and CAS # 1064698-37-8.

Pharmaceutical Manufacturing

Use of PFAS in equipment and supplies used to manufacture pharmaceutical products. Processes to make pharmaceuticals require a high degree of cleanliness, purity, chemical stability and thermal resistance necessitating the use of fluoropolymers. They are commonly used in a variety of containers, tubing, filters and other processing equipment.

Chemical Production

Fluoropolymers in particular are used is a multitude of applications related to chemical manufacturing to seal equipment and containers to prevent the release of hazardous chemicals or for filtration applications to prevent air or water emissions during industrial processes. These sealant and filtration products are used during the manufacturing of many chemical and other materials, like acids, chlorine, carbon black, cement, TiO2, catalysts, mineral, polymers, fertilizers, pesticides, industrial & household cleaners, pulp & paper manufacturing and many others.

Transportation

- Fluoropolymers are necessary for additional applications in aerospace that require temperature and chemical resistance, thermal stability and high strength. Such applications include insulation for cables or gasket materials used in aircraft, spacecraft and satellites which are exposed to extreme conditions and require exceptional reliability.
- Many components and systems in automobiles require protective vents made from fluoropolymers. These vents are used to seal critical systems like headlamps, drive trains, or batteries from dirt, oils and water while allowing gases to pass through for safe, reliable performance.

Solid Waste Treatment

Fluoropolymers are used for the transformation of non-hazardous organic residues from households, industrial or agricultural generators into products which close the natural cycle to return valuable nutrients to soils contributing to soil health sustainably while supporting the carbon capture in the ground, addressing global challenges like climate change and food security.

F-gases

V. Questions - Section B - F-gas uses - Questions in relation to the use (mainly for industry associations)

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

- As a refrigerant in HVAC-R equipment.
- In fire protection applications, the fluoroketone fire suppression agent (CAS #756-13-8 with GWP<1) is used to suppress fires in enclosures that house high-value electronics or other assets that would be damaged by water sprinkler suppression systems. Common applications include electrical control rooms or underground substations, data centers, telecommunications switch rooms, computer control rooms, airport control towers, clean rooms, and computer-controlled manufacturing operations as well as in archives and museums with paper archives, historical documents, priceless works of art and antiquities where other fire protection fluids cannot be used. The fluoroketone fire suppression systems are also used in marine vessels. This material is a replacement for ozone depleting substances and compounds with high global warming potential (GWP) including halons and hydrofluorocarbons (HFCs). This product is a very low GWP (<1.0) clean extinguishing fire protection fluid.
- In building materials, a PFAS-based foam additive (CAS# 3709-71-5) is used as a foam insulation additive due to its effectiveness in reducing the foam cell size and thus the thermal conductivity of polyurethane and other rigid foam formulations. It is used in the production of rigid insulation polyurethane foam products to meet the latest EU thermal conductivity specifications (e.g., DIN EN 13165). Typical usage rate for this product is as low as 0.5% of the total foam weight and this product is used in a closed manufacturing process. The foam additive is incorporated into the final foam product.

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

No

Please specify why.

- If technically feasible, ie comply with 5 main criteria - economic, safety, energy efficiency, environment and sustainability (ease of manufacture) none of alternatives present a technically feasible alternative for all HVAC applications. Similar situation in commercial refrigeration, although CO2 and propane can cover a lot of applications. Alternatives further limited in transport refrigeration due to mobile nature and attendant safety concerns (use in ferries, tunnels etc) environment and sustainability (ease of manufacture) none of alternatives present a technically feasible alternative for all HVAC applications. Similar situation in commercial refrigeration, although CO2 and propane can cover a lot of applications. Alternatives further limited in transport refrigeration due to mobile nature and attendant safety concerns (use in ferries, tunnels etc).
- For fire protection agents, non-PFAS fire protection agents include water, carbon dioxide, dry chemical, and inert gases. These non-PFAS fire protection agents can cause corrosion, can damage equipment or valuable artifacts, can be electrically conductive, are slower drying, can leave a residue, may have higher toxicity, may require high operating pressures, and may result in higher maintenance costs. In the case of carbon dioxide systems, there are reported cases of safety incidents. The link to one such incident is here: koreaherald.com/view.php?ud=20180904000834. In the case of inert gas systems, there are extra costs required to make an inert gas system safe, including extra ventilation, extra structural strength to support the weight of the system, and more expensive testing and checkout costs. The fluoroketone fire suppression agent with CAS #756-13-8 has the highest margin of safety for human occupancy among clean agents, including inert gas.
- For the PFAS-based foam additive (CAS# 3709-71-5) we are not aware that any non-PFAS direct alternatives exist. Elimination of the additive will reduce overall performance of the foam insulation by increasing thermal conductivity and thus lowering energy efficiency of the polyurethane foam insulation. The use of the additive in addition to the foam blowing agent makes it possible to meet the latest EU thermal conductivity specifications (e.g., DIN EN 13165).

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

No

Please specify why.

- If alternatives would be economically feasible they would already be widely available, eg propane in domestic refrigeration and CO2 in commercial refrigeration. Providing an answer would require a breakdown in specific sub-sectors given the wide range of applications.
- Non-PFAS alternatives are not economically feasible in HVAC and transport apart from some niche applications.
- In the case of non-PFAS fire protection agents, the inert gases, they take up more room and that additional needed space has cost implications. The inert gases also need to displace more air to

put out a fire, so more cylinders of gas are needed and thus would results in additional costs in the event of recharge. There are also reported incidents of inert gas fire suppression systems causing damage to IT hardware. The link to one such incident is here and includes references to other such events: datacenterdynamics.com/en/news/air-conditioning-fire-suppression-took-down-australian-betting-site-tabcorp/. There are also extra costs required to make an inert gas system safe, including extra ventilation, extra structural strength to support the weight of the system, and more expensive testing and checkout costs.

V. Questions - Section E - F-gas uses

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? Yes

Data Center Cooling

Though liquids at room temperature and thus not meeting the definition of F-Gas provided, some of the fluorochemical heat transfer fluids are included in Annex 1 of the EU F-Gas regulation (i.e., CAS #1064697-81-9) and Annex 2 of the EU F-Gas regulation (i.e., CAS# 375-03-1, CAS # 163702-08-7/163702-07-6 & CAS # 163702-06-5/163702-05-4). Fluorochemical heat transfer fluids can be used for liquid immersion cooling applications in data centers. Immersion cooling is a method for cooling data center IT hardware by directly immersing the hardware in a non-conductive liquid. Heat generated by the electronic components is directly and efficiently transferred to the fluid. This reduces the need for interface materials, heat sinks, fans, shrouds, sheet metal and other components that are common in traditional cooling methods. Immersion cooling with these fluids offers many benefits compared to traditional air cooling, including increased thermal efficiency (i.e., lower power usage effectiveness or PUE) and increased performance and reliability of data centers. Immersion cooling also eliminates the need for complex airflow management. Optimized immersion-cooled data centers can lead to reductions in capital and operating expenses, as well as a reduction in construction time and complexity. The increased compute density from immersion cooling allows for more flexible data center layouts and removes barriers to data center location choices such as areas with high real estate costs or space limitations. Finally, immersion cooling with these fluids can help eliminate the tradeoff between water usage, energy efficiency and cost by eliminating the need for chillers with economizers and complex controls used in air cooling. This helps eliminate the use of water needed to cool the data center by, instead, utilizing natural water temperatures in many climates to allow for full capacity cooling without evaporation infrastructure.

Dielectric Insulating Gases

PFAS-based insulating gases (CAS# 42532-60-5 and CAS# 756-12-7) are used in gas mixtures in medium-voltage and high-voltage gas insulated power generation and distribution equipment including gas insulated switchgear and gas insulated lines in place of sulfur hexafluoride, a potent greenhouse gas with GWP of 23,500. Existing installations using gas mixtures with these insulating gases are demonstrating the potential to reduce greenhouse gas emissions by more than 99% compared to installations using SF6. Non-PFAS electrical insulation includes vacuum, interrupter/air-based technology. However, it is unlikely that the full voltage range can be covered by this technology. Furthermore, the increased space requirements of this technology when used in high voltage applications results in an overall worse life cycle management assessment compared to equipment using the mentioned insulating gas mixtures.

Electronics And Energy

V. Questions - Section B - Electronics & energy

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

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

For the applications of the fluorochemical fluids in Electronics and Energy, including solvent cleaning, carrier solvent, heat transfer, thermal testing, coating, fire suppression, data center electronics immersion cooling and insulating gases, it is possible that these products can be emitted to the air during use. However, these products are typically used in closed systems in which users manage and minimize emissions or in systems in which the fluid and vapor can be captured, collected, recycled, and re-used. The products can be filtered in-situ to extend useful life and can be recycled and reused.

Regarding the electronics cooling applications for data centers, the following comments are provided regarding “Report summary Electronics and Energy”, Section 7, “Emissions”: The text provided comments: “Currently a yearly loss of immersion cooling liquid in 2 phase systems of 1% is said to be industry best practice.” We agree this may represent current practices, however, with the desire to reduce cost and emissions, practices will be improved. It is reasonable to believe that the industry will achieve evaporative losses on the order of 0.1% per year from ongoing improvements to both tank design and operational controls (i.e., operating procedures to perform routine maintenance). Additionally, due to the anticipated increased reliability of hardware used in immersion cooling, one reference mentions a fail-in-place concept where maintenance would be delayed which could further reduce fluid loss. See the following reference: (news.microsoft.com/innovation-stories/datacenter-liquid-cooling/). This could reduce emissions to an even lower threshold.

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

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

The fluorochemical heat transfer fluids are used for liquid immersion cooling applications in data centers. Heat generated by the electronic components is directly and efficiently transferred to the fluid. This reduces the need for interface materials, heat sinks, fans, shrouds, sheet metal and other components that are common in traditional cooling methods. Immersion cooling offers many benefits compared to traditional air cooling, including increased thermal efficiency (i.e., lower power usage effectiveness or PUE) which results in increased performance and reliability of data centers. Immersion cooling also eliminates the need for complex airflow management. Optimized immersion-cooled data centers can lead to reductions in capital and operating expenses, as well as a reduction in construction time and complexity. The increased compute density from immersion cooling allows for more flexible data center layouts and removes barriers to data center location choices such as areas with high real estate costs or space limitations. Finally, immersion cooling can help eliminate the tradeoff between water usage, energy efficiency and cost by eliminating the need for chillers with economizers and complex controls used in air cooling. This helps eliminate the use of water needed to cool the data center by, instead, utilizing natural water temperatures in many climates to allow for full capacity cooling without evaporation infrastructure.

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

No

There is no substitution in the applicable use areas described for the fluorochemical fluids used in Electronics and Energy with equally high performing, technically and economically feasible products. The chemistries of the PFAS substances are key to achieve the required high performance and durability of the products in the various use areas. Any non-PFAS substance used in these applications is expected to exhibit inferior performance, and a detailed and comprehensive life cycle assessment would still need to demonstrate whether the various uses would result in a lower potential impact on the environment. Otherwise, there is substantial risk of making a non-science based and ultimately regrettable substitution. Many of these high performance and highly durable products, used in a critical environment from a health and safety point of view, have to be qualified and/or certified, which means that any different product developed, if at all possible and advisable, would need to go through a lengthy qualification process.

For immersion cooling of electronics in data centers, non-PFAS heat transfer fluids include mineral oils, synthetic oils and natural oils. These materials are prone to dissolving hydrocarbon-based polymers and are therefore less likely to be compatible with adhesives, elastomers, and thermal interface materials. Moreover, most hydrocarbons are combustible and/or flammable. Therefore,

hydrocarbons may pose an unacceptable risk to safety and infrastructure for many applications, particularly in two-phase immersion cooling. Hydrocarbon fluids with sufficiently high boiling points and flash points can be used in some single-phase applications, but they have the disadvantage of being relatively viscous (especially at low temperature) and do not evaporate readily from hardware when it is removed for service creating maintenance issues.

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

No

Why?

Often non-PFAS alternatives to the fluorinated liquids can cost as much as 10X or more versus non-fluorine containing materials. Industry is only willing to pay this premium in challenging applications where the unique attributes of the fluorinated materials are necessary. Otherwise, industry will generally use the most cost-effective solution that meets the needs of the application. In the industries in which these products are used (e.g., semiconductor, automotive, electronics, energy, healthcare, and government), the costs and timeline for research, development, testing, qualifications, and changes to processes would be significant even if suitable alternatives could be identified. Any changes would have to be evaluated to understand if more complex environmental, health and safety challenges would be created, and the increased costs would be passed downstream to customers.

In the case of immersion cooling of electronics in data centers, a more holistic view of the true value and cost of immersion cooling should consider cost on the scale of an entire datacenter, including annual savings for water and energy. Datacenters built for immersion cooling can be built in less time, require a smaller footprint, use less water and less energy to provide equal or greater computing power compared to an air cooled datacenter. The non-PFAS fluids, including mineral oils, synthetic oils and natural oils, would not be expected to have this same advantage due to the higher propensity to become contaminated and lower stability and lifetime expectations.

Finally, AmCham EU would like to note that there is an error in Appendix 1 in “Report summary F-gas uses”. Entry 24 “methoxytridecafluoro-heptene isomers”, MPHE Sion TM is NOT a fluoroketone.