AmCham EU
SPEAKING FOR AMERICAN BUSINESS IN EUROPE

# Our position

# PFAS restriction proposal

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 2019, directly supports more than 4.8 million jobs in Europe, and generates billions of euros annually in income, trade and research and development.

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# Executive summary

The European Chemicals Agency (ECHA) is currently discussing the restriction of per- and polyfluoroalkyl (PFAS) substances. To secure long-term European manufacturing, this socio-economic analysis must not only include the impact on specific applications but also the impact on transatlantic trade and foreign long-term investments. Not taking these into account will ultimately have strong repercussions on the EU's strategic autonomy and on many key policies, including the Green Deal ambitions.

Furthermore, ECHA, its committees, the European Commission and EU Member States should review the proposal's current derogations and assess their enforceability. For many strategic sectors and technologies, derogations are too short or completely missing where no viable alternatives exist. In addition, the proposal does not adequately assess the availability and viability of relevant alternatives. By way of example, further derogations and exemptions are needed for important applications in medical technology, the high-tech sector (eg semiconductors), clean energy (eg hydrogen fuel cells and batteries) and industrial manufacturing. These are among the applications that ensure the continued operation of countless industrial plants that underpin entire value chains in Europe, supporting the green transformation of industry and the goals of the Green Deal.

The restriction's framework should therefore take a proportionate approach to allow for both the achievement of the ambitions laid out in the Net-Zero Industry Act (NZIA), Green Deal and REPowerEU as well as the preservation of human health and the environment.

In summary, ECHA must amend the proposal to:

- Exclude from the scope of industrial/professional applications which are fundamental for European sovereignty and the implementation of the NZIA, as well as crucial for the cooperation established in the EU-US Trade and Technology Council (TTC) involving batteries, semiconductors/chips, heat pumps, electric vehicles, hydrogen and renewable energy.

- Ensure alignment with the main Green Deal principles including 'Energy Efficiency First', as embedded in the main legislative pieces of the REPower EU package.

- Exclude remanufactured/refurbished/repurposed products and components and allow repairability of products to further the goals of the Circular Economy Action Plan.

- Be coherent with other regulatory requirements and legislation, such as the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) Regulation and the Classification, Labelling and Packaging of Substances and Mixtures (CLP) Regulation, Fluorinated Greenhouse Gases (F-Gas) Regulation and relevant sectoral legislation[1].

- Exempt those PFAS that have not been shown to pose an 'unacceptable risk' such as fluoropolymers, which should be regulated by separate regulation, for example by targeted emissions controls. The proposed outright ban is disproportionate to the risk substances such as fluoropolymers pose.

[1] Eg Medical Devices Regulation; IVDR, Medicinal Products Legislation, ADD other relevant pieces of legislation

- Amend provisions based on incorrect technical assumptions. Accordingly, raw materials (eg fluorinated surfactants) required for the production of PFAS of low concern and which do not pose an 'unacceptable risk' (such as fluoropolymers) should be exempted.
- Include a more proportionate approach to thresholds, thereby ensuring an enforceable legislation.
- Include a general derogation for uses of PFAS at industrial sites to safeguard important value chains.
- Include a review clause for derogations in cases where no alternatives became available in the future.
- Consider new and ensure longer derogations that allow the industry to adapt or ensure the exclusion for some uses where alternatives are only at the research and development stage or not suitable in their current form (see list in the ANNEX I).

# Introduction

The relevant committees of ECHA are currently discussing a REACH restriction on manufacturing, placing on the market and use of per- and polyfluoroalkyl (PFAS) substances. ECHA defines PFAS as including more than 10,000 molecules which have very different hazard profiles. The first proposal which was submitted by authorities from five Member States to the ECHA, corresponds to a wide-range ban as it includes only three time-unlimited exemptions[2] and a limited number of very narrow, time-limited derogations for some applications (approx. 50 derogations are granted which is not a lot when comparing to the 10,000 substances impacted). Furthermore, there is differentiation between the hazard profiles of the targeted substances, their use in the economy or clearly identified risk. Such an approach does not live up to the REACH regulation's high standards and risks critical sectors' ability to contribute to a sovereign and sustainable European economy and ambitions of a low carbon future.

The proposal, particularly the restriction of PFAS in medical devices and in pharmaceutical manufacturing,[3] also poses a threat to the continued provision of state-of-the-art medical care for European residents. In fact, despite time unlimited derogation for active substances, the proposal does not allow manufacturing, R&D or packaging of final medicine and devices.

The decision to group all substances defined as PFAS together without any differentiation is without scientific rationale,[4] risks deterring future industrial investments and upending current operations in many sectors.

Not only would the impact on EU-US trade be dramatic, as the proposal would affect the Green Technology Alliance and TTC developments, but it would also shift value chains out of Europe, without any significant positive impact on the environment. In line with Net Zero Industry Act (NZIA) goals, industry must continue investing in strategic sectors, and therefore critical uses should be excluded from the legislation's scope and regulated differently. Those PFAS (as defined in the current restriction proposal) that demonstrate a hazard

[2] PPP (EU xxx/xx), BPR (XXX/XXXX) and medicinal and veterinary products (resp. XXX/XXXX & XX/XXX) Heat pumps & air conditioning

[3] While final active pharmaceuticals ingredients are proposed to be derogated, process chemicals and raw materials used in their manufacturing are not included in the derogation and therefore proposed to be banned 18 months after entry into force. The derogation also fails to extend to R&D operations, which will directly impact the possibility to carry out clinical trials in Europe going forward.

[4] EEAP (2022) Assessment Report, p. 278.

profile that is indicative of low concern, such as fluoropolymers, should be exempted or regulated separately, with a focus on additional emissions control measures rather than a production and import ban, which is disproportionate to the risk such substances pose. The paper below outlines: general consideration for the restriction proposal; concerns relating to coherence with other legislation, the scope of the restrictions, time derogations, the sustainability of production, the timelines for consultation, disproportionate threshold and enforcement, and remanufactured and repaired products; the economic impact of the proposal; and recommendations for specific sectors derogations/exemptions.

# General considerations

In the restriction, the five Dossier Submitters are right to focus on protecting human health and the environment and recognising that across the PFAS group as per the chemical definition in the proposal, certain substances may warrant restriction. However, as persistence is not a recognised hazard in the CLP regulation, persistence alone is not a justification for a restriction, particularly for substances where there are no other hazard such as fluoropolymers or fluorinated - gases.[5] From a risk management perspective, the EU should use a more proportionate approach to ensure adequate control of emissions across the lifecycle through additional requirements under other regulatory frameworks such as industrial emissions,[6] occupational health exposure limits [7]and the waste directive.

Balanced science-based regulation of PFAS in Europe would protect people and the environment from unacceptable risk while also ensuring the availability of critical substances for technological development and innovative applications. To achieve this goal, the EU should:

1. Base restriction on sound science

The restriction of PFAS must be substance related – listing specific CAS numbers and differentiating amongst PFAS where different properties and behaviours exist – and risk based (article 68, paragraph 1 of the REACH Regulation). Not all PFAS falling under the restriction proposal definition represent an unacceptable risk that [8] would justify a restriction.[9]

The restriction must also differentiate between the different PFAS groups, including fluoropolymers and fluorinated gases (F-gases), and the risks associated with their use. Potential concerns related to the production and end-of-life phase must not lead to an immediate, broad ban but should rather be addressed by other regulatory measures, as mentioned above.

2. Apply derogations for the whole value chain

[5] J.K. Anderson, et al. ( 2022), *Grouping of PFAS for human health risk assessment: Findings from an independent panel of experts*.
[6] IPPC BAT reference documents https://eippcb.jrc.ec.europa.eu/reference
[7] ECHA Valeurs limites d'exposition professionnelle https://echa.europa.eu/fr/oel#:~:text=Occupational%20exposure%20limits%20(OELs)%20are,the%20air%20of%20a%20workplace

9 EEAP (2022) Assessment Report, p.278

Where sectoral or downstream users' derogations are granted, the EU must make clear that they apply to the sector's whole value or supply chain.

The assumption that if no derogation is requested, the use or substance is automatically restricted or banned could be risky and liable to result in unanticipated societal and economic damage.

In addition, some derogations are not granted by sector but by individual product categories – medical devices, for example. There is a risk here that such specific derogations would inadvertently not cover all uses and restrict critical products to patients. This is particularly true given the difficulty to identify PFAS where CAS numbers are not provided or even available.

The PFAS restriction should also derogate critical uses of PFAS materials and fluoropolymers at industrial sites (including those that make pipes, gaskets, membranes, personal protective equipment [PPE], etc). Such a derogation could be accompanied by strict requirements around reporting and labelling.

Finally, given the multitude of small and large companies in the EU and third countries in a sector's supply chains, it is not practical to rely on all of them to request derogations; derogations must explicitly apply to whole value chains and not just to prime downstream users.

3. Acknowledge the poor availability of data for possible alternatives

The authorities from the five Dossier Submitters (Germany, Denmark, Sweden, the Netherlands and Norway) did not submit meaningful and sufficient data on the availability and/or technical feasibility of alternatives that are equivalent in terms of performance and safety and sustainability covered by performance and technology readiness.

They also did not foresee a review clause that would enable a full assessment of the viability of a transition to an alternative in a timely manner ahead of the legislation's entry into force. The absence of a proper review could jeopardise critical technologies (such as Lithium-ion batteries, cables, flame retardant plastics) and related value chains, and push even entire sectors out of Europe.

## Coherence with REACH, CLP and F-gas developments

In order to ensure an appropriate level of predictability, restrictions of substances under the proposed PFAS restriction should be based on unacceptable risks stemming from exposure to recognised hazards. As part of the Chemicals Strategy for Sustainability (CSS), a number of new hazard classes were recently introduced in the CLP regulation, including new hazard classes for persistent, bioaccumulative and toxic (PBT), very persistent and very bioaccumulative (vPvB), persistent, mobile and toxic (PMT) and very persistent and very mobile (vPvM) substances.

However, there is no hazard class for substances displaying persistent properties alone, in the absence of additional, proven concerns around bioaccumulation, mobility and toxicity. This is also reflected in the CSS communication and the commitment to extend restrictions based on the so-called generic approach to risk

management (GRA) to a range of new hazard classes, including substances that are persistent and bioaccumulative. Recognising concerns related to potential emissions at different phases of the lifecycle, a restriction on the basis of persistence alone is not proportionate. This is particularly so given the possibility of addressing eventual emissions through other legislative measures (eg the Industrial Emissions Directive).

## Scope of the restriction

PFAS are per- and polyfluoroalkyl substances and, according to the Organisation for Economic Co-operation and Development definition, they can encompass over 10,000 molecules made up by a varying number of carbons, ie from $C_1$ to $C_{>1000}$. Not all PFAS substances have the same toxicological and ecotoxicological profile. Many PFAS are persistent chemical substances that can be found in the environment (water, air, soil or sediment). Some can accumulate in living organisms and end up in the food chain, while others may be mobile and are transported over very long distances by water or air far from their source of emission.

In practice, these chemicals may have different effects on the body and the environment, and do not have the same characteristics. For example, fluoropolymers, high molecular weight substances that meet the definition of PFAS because of their structure, are nonbioavailable, and therefore, of low concern from a human and environmental health standpoint. In addition, they have a unique combination of properties used in many applications: chemical resistance, thermal resistance, dielectric properties, tribological properties (resistance to friction and wear) etc.

Similarly, some F-gases may produce trifluoroacetic acid (TFA) when they come into contact with the atmosphere. TFA is a persistent substance[10] but not toxic and hence does not harm the environment. Whilst TFA has been generally associated with PFAS so far, a recent report from the United Nations Environment Programme has even clarified that such a substance should not be considered as belonging to the PFAS family.[11] This position is also supported by the US Environmental Protection Agency that excluded TFA from the list of PFAS listed under its strategic roadmap.[12] Those F-gases contribute to limiting the global emissions of greenhouse gases from electrical equipment, the heating and cooling industry, and the automotive industry. Furthermore, technologies using the mentioned F-gases contribute to limiting emissions of other PFAS, such as CF4 and C2F6, as they require less use of raw materials (eg aluminium) and are also compatible with existing technologies and infrastructures.

As with any other chemical substance, the EU or ECHA must assess the impact and toxicity of each substance and if necessary, severely limit emissions and exposure to the population. It is understandable to try to avoid migration to more hazardous alternatives by restricting more than one substance at a time yet going from regulating a handful to 10,000 overwhelms the resources allocated to track these substances' presence and assess their potential impacts across many industries.

## Time derogations do not allow the industry to adapt

[10] Neale, R.E., Barnes, P.W., Robson, T.M. et al. (2021) Environmental effects of stratospheric ozone depletion, UV radiation, and interactions with climate change: UNEP Environmental Effects Assessment Panel, Update 2020. Photochem Photobiol Sci 20, 1–67 https://link.springer.com/article/10.1007/s43630-020-00001-x

[11] EEAP Environmental Effects Assessment Panel (EEAP) | Ozone Secretariat (unep.org)

[12] PFAS Strategic Roadmap: EPA's Commitments to Action 2021—2024

The proposal includes some use-specific derogations, extending the time before companies must switch to an alternative. For many uses, however, the period of time required for a conversion cannot be meaningfully determined due to a lack of technically mature alternatives. Even if alternatives already exist, the proposed derogation period is too short for many uses. The development and conversion of production processes as well as the development, approval and certification of products require a longer period of time in many areas than is currently provided for in the initial proposal (eg medicinal products, medical products and devices regulated under a marketing authorisation, engineering plants, chemical installations, heat pumps and refrigerants, vehicles type approvals, petroleum and mining, airplane and military related product approvals etc).

A longer general 12-year derogation appears to have been arbitrarily chosen as sufficient time to find alternative, regardless of the complexity of the applications and the status of potential alternatives. This model ignores the specificity of highly technological sectors and the (re)qualification – (re)certification time needed in highly regulated applications. Longer and time-unlimited derogations should be considered for sectors that require them.

For example, a 12-year derogation would be grossly inappropriate to identify and implement alternatives to PFAS in healthcare applications (keeping in mind that only select medical devices would benefit from the longer 12-year derogation, while others may benefit from shorter timelines or no derogation at all according to the current proposal). Even if an alternative was available and medical technology companies started preparations to replace PFAS in medical devices today, this timeline would be technically and legally challenging. According to the existing Regulation 2017/745 (Medical Devices Regulation [MDR]), material changes are not permitted. Changes to medical devices entail new conformity assessments under the MDR, which take several years, depending on their scope. For existing products, qualifying and implementing an alternative material for the marketplace can take up to 12 years, provided that there are already technically and economically feasible alternatives available. However, this is not the case for much of medical technology, and many alternatives are not foreseeable today. The final restriction must reflect this reality for the medical technology industry and other highly regulated industries. A discontinuation of life-saving technologies and services such as aorto-ostial procedures for stenting, heart valve repairing and replacement, catheters, implants, and capital equipment used in related procedures and IVD uses (eg instruments, diagnostic testing kits); will lead to:

- Undiagnosed conditions;
- An increased incidence of puncture wounds, device malfunction and/or the inability of the surgeon to sufficiently visualize the surgical site;
- An inability to manufacture critical medical technologies; and
- Some medical device procedures being replaced with much more invasive and higher-risk procedures (such as open-heart surgery) which would significantly increase patient trauma.

Even where the proposal provides some temporary derogations for the use of fluoropolymers, their effect is unclear, since it does not stipulate derogations for the required raw materials and other products involved in the manufacturing of the fluoropolymers such as processing aids and monomers. The restriction proposal's rationale is that production aids that do not contain PFAS can be used for the production of certain fluoropolymers (Polytetrafluoroethylene, Polyvinylidene fluoride or polyvinylidene difluoride, and fluorine rubber perfluoroalkoxy, etc). However, this approach fails to consider that not all fluoropolymers and not all applications can be produced without fluorinated surfactants. There is no alternative to fluorinated

polymerisation aids for the production of certain high-molecular, very pure, high-quality fluoropolymers (fine powder or dispersion), which are used in many high-tech applications. Only these substances create reaction conditions that enable the formation of the very high molecular weight chains needed during the polymerisation process. The restriction proposal's very limited exception for polymerisation aids could mean that after the transition period of only 6.5 years, the manufacture of end products containing high molecular weight fluoropolymers (eg medical devices) would no longer be possible in the EU. However, the derogations would allow these products to be imported into the EU, running counter to the EU's goal of shortening supply chains and strengthening the EU's industrial base and independency.

Further consideration is needed of additional derogations. The electronics industry is currently gathering technical information through its complex value chains to support additional derogations related to essential uses of PFAS without alternatives. These include uses in critical technologies such as lithium-ion batteries, cables, coatings, flame retardant plastics and so on. Further recommendations on derogations needed will be submitted during the consultation period.

In addition, the proposal completely ignores issues regarding the availability of spare parts or components/materials of equipment already on the market at the time when the PFAS restriction would enter into force and/or a specific derogation would expire. The availability of spare parts is critical for products with a very long life time (eg use at production sites/machinery, aerospace, military). Derogations for spare parts and products placed on the market prior to the effective date intended for reuse are critical to help achieve EU goals of avoiding premature obsolescence and for compliance with laws promoting product longevity. The concepts of 'right to repair' and allowing resale of pre-owned products have been broadly incorporated into other EU substance restrictions, and other EU REACH restrictions, and it is essential to incorporate them into the EU PFAS restriction to avoid major market disruptions. Lack of derogations for spare parts and products intended for reuse is clearly contrary the European Green Deal goals on resource efficiency and a circular economy.

## Sustainability of production for derogated sectors

The current restriction proposal contains a limited number of derogations. It is therefore unknown whether these would apply to not only companies' whole value chain but also in the future, since the socio-economic analysis does not examine whether the operation of the production facilities for those few derogated products would continue to be cost-effective in the future. There is a risk that essential applications that are currently derogated would no longer be available in the future as the production site may no longer economically viable to produce only for a few derogated uses. A holistic socio-economic analysis needs to therefore consider asset essentiality and the economic viability of a whole asset as well.

## Inappropriate timeline for consultation and input gathering

The timeline for the consultation period is challenging. Manufacturers, importers and users of complex articles (such as electronics and aerospace applications) require substantially more time to respond. The proposal greatly underestimates the burden on manufacturers and importers of complex articles to perform the due diligence necessary to identify these substances, perform alternatives analyses and submit information at the level of depth and granularity that is apparently expected.

Global suppliers are currently required by other existing rules or industry practices to either assess or communicate information about the presence of any but a small handful of the substances covered by the

proposed restriction. It is unrealistic to expect the global value chain to establish a material declaration and notification system within a short period of time that would allow them to effectively manage the proposal's notification and disclosure requirements. Even sectors with fewer original equipment manufacturers and tightly integrated and highly coordinated supply chain material tracking systems (such as automobile and aerospace manufacturing) are unable to collect the information necessary.

Moreover, by failing to properly identify substances (such as CAS Registry number, European Inventory of Existing Commercial Chemical Substances, IUPAC nomenclature, etc) within the scope of the proposal (which applies to 10,000 substances), and the lack of clarity around use and affected industries the dossier submitters deprive the interested parties of the right to have their affairs handled 'impartially, fairly and within reasonable time', in accordance with article 41(2)(a) of the EU Charter of Fundamental Rights. It is impossible for stakeholders to provide 'all information, which might have a bearing on the results' of the identified 10,000 substances and their uses.[13] Similarly, it is not credible that authorities would examine all the information carefully and impartially to deliver an adequately reasoned decision within six months and 60 days, according to the REACH consultation procedure on restrictions,[14] especially considering that the authorities have a wide power of discretion in such technical issues.[15]

## Disproportionate thresholds and impossible enforcement

The proposal's threshold concentration levels are also not proportionate and should be adjusted upward. For PFAS and PFAS polymers in imported articles, especially in complex electronics and information technology (IT) equipment, the restrictions should be proportional to the low risks and manageable releases associated with PFAS and PFAS polymers used in these imported articles. They should avoid setting threshold levels so low that the mere presence in upstream manufacturing operations (outside of the EU) would lead to cross-contamination that exceeds the threshold levels.

In addition, although the thresholds imposed by this restriction would *de jure* prohibit the production of components and finished products, as well as their import, *de facto* it would be almost impossible to make sure that products containing PFAS above a certain threshold are stopped at the EU's border, especially if these substances are in imported finished products, including complex articles like aeroplanes and automobiles. Likewise, ensuring these products are manufactured responsibly and determining which substances are used for their production would be extremely challenging. This is particularly true given the broad scope of the restrictions and the absence of identifiable CAS numbers for substances in scope.

Moreover, currently there is a complete lack of standardisation and methods relative to testing for all possible PFAS substances. Market surveillance would be impossible today, and extremely expensive once the methods are finally developed. This is because fluorine is a very difficult element to detect with off the shelf, portable

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

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

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

equipment, so highly specialised tools must be used to determine if it is present. Even then, you have to use different highly specialised tools for different PFAS depending on the size of the molecule, ie polymers versus discrete chemicals, etc. This is a massive problem with the whole idea of restricting this broad of a chemical family. We can't improve what we can't measure.

If the proposal is implemented as written, the EU risks technology transfer and loss of technological sovereignty to other producing countries, without any environmental benefit as the regulatory framework for industrial emissions in many third countries is not comparable to the ones applicable in the EU and the US.

## Remanufactured, refurbished and repaired articles

Articles previously placed on the market should be excluded from the restriction's scope. Excluding such articles is common practise under EU policy in similar settings. Unavailability of spare parts and materials for maintenance would significantly impact the life-time of especially long-lived products such as manufacturing plants, transportation vehicles – especially airplanes – just to name a few with significant impacts to society and sustainability.

For example, under the New Legislative Framework, Union harmonisation legislation applies only to new products until the products reach end users.[16] A product still in the distribution chain falls under the obligations of the Union harmonisation legislation as long as it is a new product. Once it reaches the end-user it is no longer considered a new product and the Union harmonisation legislation no longer applies.

Therefore, the following general derogations should also be added to the proposed PFAS restriction, alongside the other derogation comments:

- Spare parts for repair and maintenance for products and equipment already placed on the market.
- Re-supply of articles already placed on the market (pre-owned products).
- Recovered and/or recycled F-gas refrigerants for maintenance and repair of equipment.
- F-gases and other materials for refilling and maintenance of in Heating, Ventilation, and Air Conditioning (HVAC)/Mobile Air Conditioning (MAC) and Tailor-Made Solutions (TMS) RHVAC/MAC/TMS EV equipment already on the market

These derogations are critical to help avoid premature obsolescence and comply with laws promoting product longevity and circularity. The concepts of 'right to repair' and allowing resale of pre-owned products have been broadly incorporated into other EU substance restrictions and REACH restrictions until now, and it is essential to incorporate them into this EU PFAS restriction as well to avoid major market disruptions.

[16] See Blue Guide at 15 ('Union harmonisation legislation applies when the product is placed on the market (or put into service) and to any subsequent making available until the product reaches the end-user.

# Assessment on the impact on fundamental sectors of the EU-US economy

The draft restriction will result in a ban on the production, use and import of PFAS within 18 months of the date of entry into force. Limited derogations of 5 and 12 years with an 18-month transition period are defined according to applications within the different sectors and product categories, and without a review clause. Not granting enough derogations could weaken the European production of certain key substances, as the availability of derogations for only a limited number of applications would still incentivise producers to favour the production in other markets/geographies. This approach could also impact the achievement of wider European objectives such as those in the Chips Act, the Smart Mobility agenda and the NZIA as well as Fit for 55 and REPowerEU (eg in case of heat pumps). Under the current proposal, there is no exemption for electronics and only a limited exemption (12 year derogation with 18 month transition period) for semi-conductor manufacturing. Additional derogations for electronics will be needed.

If adopted as it stands, this restriction could endanger Europe's industrial ambition in the fields of not only batteries, semiconductors, electric vehicles, renewable energies, hydrogen, but also water treatment, building insulation, military and defence, heat pumps, transportation, electronics and digital technology. It would also affect all operations in the industrial sector, especially in the chemical industry, medical device sector including In Vitro Diagnostics (IVDs), and the healthcare and human and veterinary pharmaceutical sectors, risking patients' access to medicines and treatments.

This proposal could stifle reindustrialisation and the continuation and future development of existing value chains in Europe, drastically impacting trade with the US and investments from US companies into the European economy**.** The uncertainty already created by the proposal would make it highly likely to impact all investments in Europe. American businesses would be discouraged from investing in new factory or production units in Europe due to the pending risk of a ban on production, use and sale of their products in such a short time frame.

As mentioned above, all industries use some of the substances included in the PFAS definition because they bring essential advantages in terms of performance, reliability and/or safety. The restriction should more specifically target consumer uses and professional uses with high potential for exposure. Similar to other restrictions, industrial uses should be derogated where no alternatives exist. Review periods should be built into the restriction to allow for changes.

Some examples of sectors and applications that would be heavily impacted include:

- Electrical cables in any industrial equipment, consumer electronics, planes, cars, sensors, condition monitoring and aerospace equipment.
- The production of chemicals, including chlorine.
- Semiconductor manufacturing and use.
- Nuclear reactors, renewable energy production (wind turbines and photovoltaic panels) and in energy distribution (pipelines etc).

- Essential components used in electronic devices (eg mobile phones, computers, servers, internet equipment etc).
- Flow batteries and lithium-ion batteries.
- Corrosion protection, anti-fingerprint coatings, pressure containment and chemical fluid dynamics (eg pipes, pumps, valves) in any chemical or industrial site (including but not limited to semiconductor fabrication plants).
- Sealing applications in the processing industry (eg food production, chemical, refining, petrochemical and pharmaceutical processes, semiconductor production, petroleum) and in transportation (eg cars, trains, aerospace) as well as in sealing applications in aerospace components such as fuel lines and hydraulic lines for landing gear.
- The production of semiconductors as critical uses of PFAS are found in process chemistries, semiconductor manufacturing equipment, semiconductor manufacturing infrastructure, semiconductor manufacturing support equipment and semiconductor devices.
- High-tech non-invasive surgery equipment, such as endoscopy devices.
- Implantable medical devices, for example cardiovascular stents.
- The production of green hydrogen, with polymer electrolyte membrane electrolyzer technology or alkaline electrolysis technology, which uses a lot of pipes and conduits and coatings to manage corrosion. No fluoropolymer means no green hydrogen production by any of the existing technologies. Therefore, the production of variants like blue and pink Hydrogen, which would support the transition, would be impossible to produce since their supply chain and production processes are dependent on components containing PFAS.
- High-performance lubricants used in the medical field for applications related to distribution (eg compressor, valves, fittings).
- The aerospace and defence (A&D) sector.
- Commercial aircraft and defence products (eg helicopters, aircraft, satellites), maintenance and repair services and sales of spares.
- High-performance lubricants.
- Fluoropolymers and fluoro-elastomers used as sealing materials in oil and fuel flow systems.
- Specialty coatings which provide wear and abrasion resistance in harsh A&D operating environments.
- Professional fabric technology for personal protective equipment, emergency services, defence sectors etc.

- Mobile air conditioning systems for passenger vehicles, mobile machinery and commercial transport including of fresh goods.
- Refrigerated transports for medical supplies and vaccines.
- Heating, cooling and refrigeration.
- Heat pumps and insulation foams to improve the sustainability of building stock in the long term.
- Military and defence applications, where PFAS and especially fluoropolymers are required to obtain the required performance and precision.
- Fluoropolymer membranes to deliver the combined properties needed for economics of scale, and lifetime and separation performance for water and wastewater treatment.
- Human and veterinary medicines and vaccines, including active substances and their manufacturing, their packaging and delivery devices, and R&D and clinical trials.
- Sealing applications in the processing industry (eg food production, chemical and pharmaceutical processes, semiconductor production) and in transportation (eg cars, trains, aerospace).
- Critical medical products and PPE to ensure patient safety, health security and occupational health.
- Rubber seals and hoses in high-pressure/high-temperature hydraulic systems or combustion engines used in machinery.
- Non-metallic, heat and friction-resistant components in engine compartments.
- Various non-metallic spare and replacement parts of long-life goods like industrial machinery (more than 20 years of useful life) currently in operation.
- Natural Gas liquefaction, Power Generation with Natural Gas, Power Generation with Hydrogen.
- Petroleum and mining (flexible pipes, O-rings, packers).
- Condition monitoring, sensors and other emission control systems eg mercury and $SO_2$.

Various trade associations are assessing the socioeconomic impact on their sectors and presenting data to the authorities as input to the public consultation, including Hydrogen Europe, Applia, Fluoropolymers Product Group (FPG), The European FluoroCarbons Technical Committee (EFCTC), The European Automobile Manufacturers' Association (ACEA), European Aerospace, Security and Defence Industries (ASD), AnimalhealthEurope, European Federation of Pharmaceutical Industries Associations (EFPIA), European Association of Automotive Suppliers (CLEPA), Committee for European Construction Equipment (CECE), MEdTechEurope, European Partnership for Energy and the Environment (EPEE) and many more. Some of those assessment data are already available.

# Conclusion

PFAS offer unique capabilities and have been originally designed to address specific product performance challenges/risks. Restricting their use without fully analysing the impact across all affected value chains, will damage European industry, causing uncertainty and stalling the development of existing products, as well as their future use in innovative technologies that have yet to be invented.

While the PFAS restriction proposal rightly aims to protect human health and the environment, ECHA has a chance now to do so while also maintaining European competitiveness. The agency should reconsider the scope of the PFAS restriction proposal to preserve EU strategic autonomy and maintain EU-US trade. If implemented as written, the restriction would hinder reindustrialisation and the continuation and future development of existing value chains in Europe, drastically impacting trade with the US and investments from US companies into the European economy. Likewise, the proposal should also: ensure consideration and coherence with other pieces of legislation and regulatory requirements such as the REACH, CLP and marketing authorisation requirements for medicines; provide time derogations that allow the industry to adapt; include a more reasonable timeline for consultation and input gathering; and specify more proportionate thresholds and feasible enforcement.

# ANNEX I – Requests for specific sectors

## Semiconductors: longer derogations periods when alternatives exist but need evaluation or total exemption where an alternative is not viable.

Semiconductor devices (also known as chips or integrated circuits) are essential components of electronic devices. Semiconductor devices are extremely complex to manufacture, with leading devices requiring more than 2,000 process steps, hundreds of production materials and approximately 26 weeks to manufacture and test. They require process chemicals, manufacturing equipment, manufacturing infrastructure, manufacturing support equipment and semiconductor devices which contains PFAS.

PFAS provide specific and unique capabilities within the Semiconductor industry that through its own research has identified limited opportunities to replace with non-PFAS alternatives. Fundamental research will be necessary for the industry to invent non-PFAS alternatives. Without PFAS, the ability to produce semiconductors (and the facilities and equipment related to and supporting semiconductor manufacturing) would be put at risk. Considering that the semiconductor industry was estimated as having global sales of $574 billion in 2022, restricting the industry's ability to use PFAS in this way would have severe economic impacts, especially when considering the loss of device functionality that could occur if chip supply is disrupted.[17]

## Electronics: staggered approach allowing more derogations timelines & exclusion for spare parts

The electronics sector is faced with unique challenges in assessing PFAS uses and potential alternatives, due to its complex value chains and extensive uses and applications. The industry needs additional time to provide comprehensive information during the consultation period and clarity on the possibility to extend derogations. The restriction should be amended to provide for an additional initial, upfront-phase-in period of five years, along with a process for evaluating additional post-processing derogation requests for the sector for PFAS used in the manufacture of electronic and IT equipment and in finished electronic and IT equipment imported, marketed and used in the EU. Redesign of products must be considered as it was for the EU RoHS phthalate restriction, which provided a transition time of four years and the EU Battery Regulation final draft requirements impacting product design will provide forty-two months.

The current proposal only allows for a five- or 12-year derogation period for specific PFAS use after the 18-month transition period. Many of the uses in electronics need more derogations in addition to more time for the specified derogations to find or develop an alternative material. In addition to a longer phase-in period for electronics and subsequent opportunity to request derogations after further investigation, the PFAS restriction should include a process to allow industry to renew the derogation period after the currently proposed five or 12 years has expired.

To accomplish objectives including those in the Circular Economy Action Plan, used products and spare parts need broad exclusions and sufficient derogations to avoid interruptions in the IT sector. The ability to trade and

[17] SIA PFAS Consortium The Impact of a Potential PFAS Restriction on the Semiconductor Sector Report No. 2022-0737 Rev. 0 Project No. REG4720-001

sell used components and equipment is an essential element of the growing circular economy. As in other EU material restriction programs, the Commission must provide a generally available derogation to enable the IT sector to access spare parts intended for use in any equipment manufactured prior to the effective date of the proposed restriction. This equipment involves a significant capital expenditure and if properly maintained, can continue to productively operate for many years, well after the likely effective date of the restriction. The proposal should exempt spare parts for equipment produced before the effective date to avoid premature obsolescence of legacy equipment. Products with PFAS already on the EU market need a derogation to be re-supplied to a new user after the compliance enforcement date for reuse as a second-life product. In addition, the proposal should allow a longer transition time of an initial of five-year derogation for PFAS used in electronics/IT equipment manufacturing and in finished electronics and IT equipment that are imported, marketed and used in the EU. In addition to these derogations, the electronics industry is currently gathering technical information to support additional derogations related to essential uses of PFAS without alternatives, among others.

The derogation requests above are fully justified because PFAS use in the Electronic and Electrical Equipment sector is a minor contributor to PFAS releases in the EU (1%), particularly in light of the massive socioeconomic impact that these restrictions might have. The restriction as currently worded could cause severe gaps in the availability of electronic and IT equipment in Europe as manufacturers, importers and distributors would struggle to find suitable alternatives for PFAS used in their products.

## Hydrogen: exemption for fluoropolymers

Electrolysers and fuel cell applications, the hydrogen industry's fundamental technologies, use fluoropolymers. In Proton Exchange Membrane (PEM electrolysers and fuel cells, fluoropolymers form the core of the stack – the membrane which isolates the electrodes from each other electrically, thus preventing a short circuit; acts as the electrolyte and conducts protons from the anode to the cathode; and provides a mechanical barrier to the Membrane Electrode Assembly (MEA), in particular to prevent mixing of hydrogen and oxygen. Fluoropolymers are also used to form membranes in the chloralkali electrolysis industry (where its use helped eliminate the use of environmentally harmful mercury cells), in direct-methanol fuel cells, in anion exchange membrane (AEM) electrolysers and are an integral part of the alkaline electrolyser manufacturing process. Moreover, fluoropolymers are further used, among other, as coatings, sealants, valves, fittings and gasification separating membranes.

As per research conducted by Hydrogen Europe, there is no alternative available today or in the near future that can substitute the performance requirements of the industry[1]. A rushed PFAS ban without granting any exemption for applications in the hydrogen sector would have destructive effects on the industry's €30-billion worth of investment in a decade (only including electrolysers and fuel cells). Such a ban would also jeopardise up to 200,000 direct and over 260,000 indirect jobs within 10 years in a market with a potential value of €820 billion employing 5.4 million jobs by the middle of the century.

Hydrogen industry therefore is requiring an exemption of fluoropolymers used across the hydrogen industry supply chain. This exemption should be linked with appropriate regulation set up to both limit emissions in fluoropolymer production stage and foster recovery of materials at end of life to the largest extent possible.

[1] Hydrogen Europe Hydrogen Europe position paper on PFAS ban

## Human and veterinary medicines: exclusion

The restriction as currently worded would cause long-term unavailability of the vast majority of human and veterinary medicines, including vaccines for all therapeutic areas in Europe and beyond. Substances such as fluoropolymers and fluoroelastomers are indispensable in production lines as they prevent contamination of medicines. Alternatives are not immediately available, while substitution would require a completely new, expensive build-up of production equipment and lines, which could take years. Additionally, in this highly regulated sector, such changes would require full validation and regulatory inspection and approval. Some chemicals used as starting materials or intermediates in the synthesis of active pharmaceutical ingredients (APIs) qualify as PFAS under the restriction's definition; any ban would automatically ban production of those APIs and the medicines they help produce from the EEA, despite the time-unlimited derogation of the final API. For other substances used in synthesis and manufacturing, no alternatives are currently available, and any changes would also require regulatory approval.

The same is true for primary packaging materials in contact with the medicines and for drug delivery devices: these have to comply with stringent requirements for non-interaction, alternatives are not readily available, and any substitution would require regulatory approval. Product & Process Oriented Research & Development (PORD) activities are currently not derogated from the scope of the proposed restriction, which means that under the current proposal any development involving a PFAS API would be banned 18 months after Entry Into Force and all the studies and clinical trials would be required to be moved outside the EEA. Collectively, this would result in severe shortages of medicines in the EU – some of which might be permanent and push production out of the region, contradicting the Commission's aims to re-home pharmaceutical production and supply.

Finally, there are several very specific derogations being proposed for Medical Devices. This does not go far enough and would mean to leave millions of EU patients without access to their medicines. For example, PFAS substances (primarily Polytetrafluoroethylene, PTFE) are used in medical devices such as prefilled or reusable pen devices; these uses are not derogated in the current proposal. PTFE brings several usability functions to the device and while alternatives are being sourced, the industry will require the longest possible derogation. The currently worded restriction would automatically ban production and marketing of those devices from the EU thereby severely impacting the EU medical device manufacturing industry and EU patients currently using them.

## Medical devices: extended timeline and mechanisms to allow continued use in absence of suitable alternatives

PFAS are used in medical technologies as they have a combination of properties no other materials/chemicals have: enabling strength, flexibility, durability, lubricity, biocompatibility, chemical compatibility (with other device materials, processing chemicals and sterilant/sterilisation methods), and processability which all allow minimally invasive surgeries and improve patient outcomes. There is often no viable alternative to the use of PFAS in many medical technologies and their packaging that would deliver similar functionalities or deliver equivalent safety or quality requirements. In addition, medical technologies are strictly regulated under sectorial legislation and where changes in the chemical or material composition occur, long validation processes are triggered. It is estimated that development, validation, clinical studies, and regulatory approval of material substitution in implantable medical devices would take approximately 20 years for a single device. Currently, there are no alternatives that meet all these properties and/or have successful clinical history like fluoropolymers. Mechanisms need to be in place where there is no alternative or where an alternative cannot

be validated within the proposed transitional periods to ensure continued patient access to vital medical technologies.

## High-performance applications in construction machinery: time-unlimited derogation

The heat and friction resistance of some PFAS make them effective at creating long-lasting and durable components in high-performance applications. Not having these materials available increases the frequency of maintenance activities (eg replacing worn-out seals) and creates additional cost and waste. Furthermore, less durable components increase the risk of premature failure, potentially contributing to accidents (eg pinhole leaks in hydraulic systems due to weaker seals and hoses). Consequently, the requirement to phase out potentially harmful chemicals contradicts other sustainability goals like having long-lasting products and preventing waste.

Some derogations were proposed for the automotive industry, eg for sound-absorbing foams in engine compartments and refrigerants (F-gases) for mobile air conditioning systems. However, these components and systems are not exclusively used by the automotive industry but also by manufacturers of mobile machinery for mining, construction, demolition, material handling and road-construction. As the volumes of these machines are dwarfed by the volume of automotive vehicles, these components' suppliers have no incentive to develop specialised versions of their products for the machinery industry. Any derogation granted to the automotive industry needs to be expanded to other industry branches using the very same components and systems to prevent a cost explosion or unavailability of components in the aforementioned sectors.

## A&D sector: exclusion

Aerospace and Defence (A&D) products have to fulfil significant technical, reliability and safety requirements. To ensure that aerospace products are safe and reliable, they must meet airworthiness regulations globally, which require a systematic and stringent framework to qualify all materials and processes. These must meet strict safety requirements that are subject to independent certification and approval through different safety agencies. A&D companies are responsible for the qualification, validation and certification of the products that they develop. The overall substitution timeline for the entire process from development to industrialisation is uncertain for many uses because the alternatives that would ultimately need to be implemented have not been identified for many applications or may not even exist.

The state of available technology today is similar to that for hex chrome uses in the late 1980s, when the aerospace sector first started alternative development efforts – alternative are still not available for all uses over 30 years later. Thus, in this case, development could take up to 15 years or even longer. While some uses may be fully substitutable in a shorter time, it is not possible to predict with certainty which ones. When it comes to the approval of materials used in the maintenance and/or repairs of A&D products, the same rigorous processes have to be followed.[18]

As a more concrete example, with regard to the delivery of aircraft, a single component containing PFAS that does not have a non-PFAS alternative and does not have a derogation could prevent the import of an entire

[18] Paper on substitution timelines, Global Consortium for Chromate Authorisation (GCCA)

aircraft into the EU. Given the specifics of the aerospace sector, finding alternatives could take much longer than 10 years to fully develop, qualify, certify and industrialise. In addition, the availability of spare parts need to be guaranteed for several decades.

The A&D industry continue to diligently pursue alternatives. However, regulators must understand that for many A&D products it may not be feasible to make certain changes due to the complexity of ensuring that no negative impacts are introduced into the designs already in place.

## Heating, cooling and refrigeration sector: exclusion

This sector uses F-gases as refrigerants contained in heating, cooling and refrigeration products. PFAS restrictions may apply to the refrigerants and to the products' components.

When used as refrigerants, PFAS should be considered as low risk, as their emissions have already been proven to be controlled effectively by the EU Fluorinated Gases Regulation, which regulates and monitors their effects. In addition, not all F-gases break down into substances like Trifluoroacetic acid (TFA), and some gases are not classified as PFAS according to the proposed definition. REACH's restrictions on F-gases undermine the rollout of renewable energy heat pumps and discourage research and innovation in Europe, to the detriment of its climate, environmental and economy.

Regarding their use as components in heating and cooling products, PFAS have unique properties that allow them to perform reliably in high-pressure extreme environments (seals, O rings, gaskets, lubricants etc.) and filter to ensure indoor air quality.

In addition, the proposed PFAS REACH restriction could potentially generate a conflict with the EU Taxonomy. This conflict arises as the EU Taxonomy imposes a limit on the Global Warming Potential (GWP) of refrigerants utilised in datacentre cooling systems, specifically not surpassing 675. Failure to comply with this standard will lead to official recognition of businesses as investors in un-sustainable infrastructure. It is essential to consider that a significant proportion of low GWP refrigerants contain per- and polyfluoroalkyl substances (PFAS). As a result, the continued utilisation of low GWP refrigerants within the EU might be subjected to questioning and evaluation.

## Electrical switchgear: exclusion

This sector uses F-gases as insulating medium for high voltage equipment as well as for specific application for which no substitute is existing nor as demonstrated to be feasible. PFAS restrictions may apply to the insulating gas and to the products' components.

When used as insulating gases, PFAS should be considered as low risk, as their emissions have already been proven to be controlled effectively by the EU Fluorinated Gases Regulation, which regulates and monitors their effects. The PFAS insulating gases have demonstrated to efficiently replace Sulphur hexafluoride (SF6), a greenhouse gas, with a very high global warming potential (24,300 times that of CO2) in high voltage switchgear to cover all voltage level in Europe and have been financed by several EU LIFE Project funds. The time-limited restriction proposed on this technology would lead to a stop to the only technology who has demonstrated a capacity to fully substitute SF6 in the EU. The proposed timeframe is indeed not sufficient to assess and validate

the efficiency and climate impact of alternative solutions. REACH restrictions on F-gases undermine the rollout of an SF6-free grid expansion and consequently the rollout of renewable energy.

Regarding their use as components in switchgear, PFAS have unique properties that allow them to perform reliably in high-pressure and high temperature extreme environments (seals, O rings, gaskets, lubricants etc.). Those property are essential to enable a reliable and safe operation of the EU electrical network. They are also used in circuit-breaker, with PTFE (a solid PFAS) nozzles, to make possible the electrical arc quenching. Without the PTFE nozzle no gas circuit breaker could be available, and the Electrical Network could not be efficiently protected.

## Automotive: exclusion from scope of fluoropolymers and elastomers, long transition for air-conditioning

The PFAS REACH restriction is expected to have a major impact on the automotive industry, as the industry is a major downstream user of many PFAS, including fluoropolymers, fluorinated gases and short-chain PFAS. Fluoropolymers are used for several key technical components, such as gaskets, hoses, joints, o-ring, seals, cords, cables, or sleeves. F-Gases are used in the air-conditioning systems. The current proposal shall allow derogations for such uses, whereas alternatives are not readily available and do not perform adequately to be qualified.

In the context of this derogation, the automotive industry needs an alternative implementation approach that integrates the technical and economic constraints on the one hand and preserves the objectives of electromobility. Essentially, to preserve the Smart Mobility agenda the Automotive industry is engaged into, fluoropolymers (including fluoroelastomers and perfluorpolyether) shall be removed from the scope of the restriction. Alternative risk management options for controlling emissions during the manufacturing phase should be implemented (through BREF and BAT) as an alternative to a restriction on fluoropolymers and fluoroelastomers.

Similarly, a more reasonable approach should be envisaged for fluorinated gasses (7 to 17 years derogation), since the large majority of cars in Europe are equipped with F-Gases in their Airconditioning systems a sufficiently long derogation period for Mobile Air Conditioning should be ensured, especially for vehicles already type approved, while a total exemption for electric compressors for all types of vehicles shall be foreseen.

## Low-pressure spray foam (LP SPF): exclusion

While building insulation foam is mentioned for a potential derogation, low-pressure spray foam (LP SPF) in building and construction for sealant, adhesive & insulation uses are not. LP SPF is unique in its portability for required use in critical spaces where other insulation products will not work (eg building insulation, food and medical cold storage and cold transportation, and in industrial pipe insulation particularly for cryogenic applications at liquified natural gas terminals).

Ultra-low GWP HFOs are used in spray polyurethane foams to enable their insulating and structural properties. Spray polyurethane foams comprise much less than 3% of total HFO global use. Due to regulation under the Montreal Protocol and Kigali Amendment, all foams have moved to HFO blowing agents where critically necessary to maintain insulation performance standards. LP SPFs are the smallest market share of all foam types in the category.

HFOs and hydrochlorofluoroolefins (HCFO) are critical components in high-performance, niche use insulation and SPF's sealant applications. They reduce thermal conductivity within the closed-cell foam structure and across surfaces, insulate and assist with polyurethane foams' superior adhesive qualities while allowing the products to air seal, reducing unnecessary air infiltration. HFO enables insulation performance that is 50% or greater than water or other not-in-kind blowing agents. The HFOs have low thermal conductivity which resist the transfer of heat, creating an ideal insulation for important building and infrastructure in extreme temperatures.

HFO is irreplaceable when used in these critical closed-cell LP-SPF products and applications. There are no known nor anticipated viable alternatives to these insulating compounds, which have been proven to be safe for human health and the environment. Any reduction of output from the niche LP SPF industry would decrease the pace at which Europe is able to decarbonise its building stock and reduce energy use, negatively impact the food and medical cold chain and lead to unintended environmental consequences, as each alternative product has its own drawbacks and suboptimal functional performance compared to LP SPF products.

## Transportation sector – refrigerants in Heating, Ventilation, and Air Conditioning (HVAC)/Mobile Air Conditioning (MAC) and Tailor Made Solutions (TMS) electric vehicles: derogation until 2050

Efficient and safe transportation in the EU is critical/vital for reaching objectives of the EU Green Deal and wider EU polices (REPowerEU, etc.). Nowadays, EU road transport was responsible for ca. 20% of CO2 emissions in EU (14% for cars & vans).[19] 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 CO2 emissions) and carbon neutrality by 2050(E).

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

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 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 commercialising of new refrigerants distracts and uses important resources that manufacturers need for their primary goals - the rapid development and

[19] T&E Campaign Transport & Environment (T&E) campaign group.

commercialisation 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.

## Insulation foam blowing agents: time-unlimited derogation

Innovative '4th generation', ultra low GWP F-gases foam blowing agents for various insulation products, including in-situ formed low-pressure PU foams (PUR/PIR)[20] as well as other polyurethane foams required for insulation of home appliances, transportation and industrial sectors. In particular, where thinner insulations layers are required due to space constraints (transportation, boats, trucks, etc.) or for higher energy efficiency performance (10-15% increase in energy performance (superior lambda) and 20% higher R-value for less thickness) There are also non-toxic, non ODS, low-GWP and non-flammable gases that are not considered volatile organic compounds (VOC).

As for *in-situ* foam, whether sprayed or dispensed, the blowing agent must not be flammable under normal application conditions. Use of flammable agents such as pentane (hydrocarbon) is not possible for board/blocks insulation foams required for better fire rated products (example?). This will also require significant investments respective production line complying with the ATEX Directive[21] rules.

Developing and registering new molecules, followed by testing and certifying a new low-pressure spray PU foam product for the industrial and construction market, requires at least 12 years. Therefore, the use of HFO-1234ze(E) HFO1336mzz (E) and (Z) and HCFO-1233zd(E) as foam blowing agent in low-pressure spray PU foams for use in all industrial, appliances, transportation and construction applications should be given time-unlimited derogation in the PFAS restriction in question.

## In Vitro Diagnostics (IVDs)

PFAS materials are widely used in IVD reagents and manufacturing processes for their material compatibility, inertness, and low coefficient of friction. Use in manufacturing includes tubing, O-rings, Teflon stir bars, greases, water treatment, etc. Unfortunately, no derogation has been proposed for these use cases. Not having a derogation to produce IVDs using PFAS materials could have a significant impact on the supply of IVD reagents upon the effective date of the restriction.

## Derogation for PFAS Use for Research and Development

Chemical use for R&D purpose is generally with small quantities, which are unlikely to result in significant human or environmental exposure. Under REACH, there is no obligation to register substances in amounts below one tonne a year. In addition, substances used in scientific research and development in amounts of less than one

[20] See on technical specifications *Closed- and Open-Cell Spray Polyurethane (PU) Foam* (PU-Europe)

[21] Directive 2014/34/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to equipment and protective systems intended for use in potentially explosive atmospheres (recast)

tonne a year are also exempted from EU REACH authorisation and restriction. The same rules and principals need to apply for PFAS research and development to support innovations of alternative materials.

## Oil and Gas

Certain PFASs provide optimal operating parameters for Subsea Flexible Pipes in offshore oil and gas fields. These pipes, made of polymeric barriers and corrosion-resistant steel wires, are essential for field development. Fluoropolymers like polyvinylidene fluoride (PVDF) and polytetrafluoroethylene (PTFE) are crucial for safety in flexible pipe construction. There are currently no substitutes for these materials, and restrictions or bans would impact energy affordability and security. PVDFs are the only solution for High Pressure High Temperature (HPHT) applications and to date, there are no alternatives. Barriers in flexible pipes comprised of PVDF are used between 90-130°C, while PFASs free alternatives, polyethylene and polyamide materials, are limited and used in only lower temperatures (between 60-90°C).

In addition, various PTFE-based sealing elements are typically used on the interfaces between metallic components. Restricting PVDF and PTFE would disrupt European manufacturing, supply chains, and result in significant economic impact. Despite the proposed derogation for petroleum and mining industry, oil and gas exploration and production would be still impacted due to disruption in the supply chain, shortages in raw materials caused in the production of flexible pipes. The existing and new oil and gas fields rely on these products as enabling technology. During the lifetime of a field, some replacement products and maintenance parts are required. If the industry is not able to supply necessary spares, this may lead to premature field closure which could affect energy security and energy affordability for decades to come. In most cases, whenever alternative materials are technically feasible, these are already in use. Furthermore, materials considered as alternatives in the proposal are not technically feasible replacements for the abovementioned application. Whereas, as acknowledged in section 2.15 of annex E of the restriction proposal, the development of alternative products could take several decades, if even possible.

## Derogation on Personal Protective Equipment (PPE) based on EU legislation

A derogation such as the one on Personal Protective Equipment (PPE), referring to the Regulation of 2016/425 on PPE, this would mean that the derogation would only be applicable for the PPE for the EU market and certified in the EU for the EU market. This would mean that producer of PPE for other markets such as the US (eg certifying according to National Fire Protection Association (NFPA) standards or according to Occupational Safety and Heath Adiministration, OSHA) would not be derogated. Therefore, the use of A PFAS for an equivalent use, would be restricted which may impact detrimental to trade, in responding to a crisis like (COVID-19) and against the goals of EU4Health.