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White Paper for EU Annex XV Restriction Report and under REACH

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I. Comment on Annex XV Report Scope

The current Annex XV Restriction Report (“Annex XV Report”) proposes to restrict “any substance that contains at least one fully fluorinated methyl (CF₃-) or methylene (-CF₂-)” (Agency, 2023). This definition is used due to concern with safety profiles of these **per- and polyfluoroalkyl substances (“PFASs”)**. Specifically, that they are, or ultimately transform into, persistent substances; are soluble and mobile in water and thereby able to contaminate surfaces, ground- and drinking water or soil; and are toxic and/or bio accumulative, both with respect to human health as well as the environment (Agency, 2023).

This definition of PFASs communicates that the compounds under this term share the same structural trait of having a fully fluorinated methyl or methylene moiety. However, it does not inform whether a compound presents risk or not. In this broad definition, there are distinct substances with very different properties: polymers and nonpolymers; solids, liquids, and gases; persistent and nonpersistent substances; highly reactive and inert substances; mobile and insoluble; eco-toxic and nontoxic chemicals. In addition, this definition covers a broad range of molecular structures- neutral, anionic, cationic, aromatic, low or high molecular weight- and therefore diverse physical, chemical, and biological properties. For all of these reasons, the definition of PFASs is too broad, and the chemicals it covers should be considered in separate groups for risk assessment and management.

One unique category that should be separated out for risk assessment and management is fluoropolymers. Fluoropolymers are a class of materials with high molecular weight. Examples of fluoropolymers are: polytetrafluoroethylene (“PTFE”) CAS # 9002-8-0 (CF₂CF₂)_n; perfluoroalkoxy alkane (“PFA”) CAS # 26655-00-5 (CF₂CF₂)_n-(CF₂CF(OCF₃))_m; and fluorinated ethylene propylene (“FEP”) CAS # 25067-11-2 (CF₂CF₂)_n-(CF₂CF(CF₃))_m. Fluoropolymers have unique properties as a result of their very high molecular weight, generally over 100 kg/mol. Each repeating unit of a fluoropolymer has an extremely strong carbon-fluorine (C-F) bond, in fact the strongest bond that can exist between C and another atom, making them highly stable materials over a very wide temperature range (Olabisi & Adewale). In addition to the thermal stability, fluoropolymers also have high chemical, oxidative, hydrolytic, and biological stability. PTFE is inert inside the body, without degradation, and is commonly used in heart stents and hernia meshes (Ünek, et al., 2019). The size of the molecule makes it impossible for the fluoropolymers to cross cell membranes. In addition, fluoropolymers are inherently non-flammable, and are highly resistant to degradation. The polymeric materials have negligible residual monomer and/or oligomer content, and low to no leachable materials (Gangal & Brothers), making the risk of ground water contamination negligible. As a result, fluoropolymers do not present significant toxicity concerns and cannot degrade into other PFASs.



2225 W. Chandler Blvd | Chandler, AZ USA

It has been widely recognized that certain chemical properties, specifically molecular weight, limit the ability of a chemical to cross the cell membrane and therefore limits its bioavailability. Examination over time has resulted in a collection of data to relate the chemical properties and structure of a given chemical to its hazard potential. These factors support the “polymers of low concern” (PLC) criteria as defined by the Organization for Economic Cooperation and Development (OECD) (Development, 1993 Apr), which have been accepted by Australia, Canada, China, Japan, Southern Korea, Philippines, New Zealand, Taiwan, and the United States (Deloitte, 2015). The full PLC criteria are detailed in the cited references (Development, 1993 Apr) (Deloitte, 2015), but include molecular weight, ionic character, reactivity, and residual monomer content, to name a few. Fluoropolymers satisfy the PLC criteria and are as such considered to be “low concern” to human health and the environment (Henry, et al., 2018).

The physical-chemical properties of fluoropolymers prevent bioavailability, bioaccumulation, toxicity, and degradation. Fluoropolymers are also not water soluble, and not subject to long-range transport. Due to the large size of these molecules, fluoropolymers cannot cross the cell membrane (Henry, et al., 2018). Based on review and assessment of fluoropolymer toxicity data, human clinical data, and physical, chemical, thermal, and biological data, research has concluded that fluoropolymers are distinctly different from other nonpolymeric PFASs (Korzeniowski, A critical review of the application of polymer of low concern regulatory criteria to fluoropolymers II: Fluoroplastics and fluoroelastomers, 2023).

Grouping fluoropolymers together with all classes of PFASs for a single approach to structure-hazard assessment based on persistence alone is therefore not scientifically appropriate. For this reason, we strongly believe that a distinction must be made within the definition of PFASs included in the Annex XV Report , and that the following fluoropolymers should be excluded from the proposed restrictions:

1. polytetrafluoroethylene (“PTFE”) CAS # 9002-8-0 (CF_2CF_2)_n;
2. perfluoroalkoxy alkane (“PFA”) CAS # 26655-00-5 (CF_2CF_2)_n-($\text{CF}_2\text{CF}(\text{OCF}_3)$)_m; and
3. fluorinated ethylene propylene (“FEP”) CAS # 25067-11-2 (CF_2CF_2)_n-($\text{CF}_2\text{CF}(\text{CF}_3)$)_m

This distinction is scientifically supported as large molecule fluoropolymers have been demonstrated to be safe and do not pose significant risk to human health (Korzeniowski, A critical review of the application of polymer of low concern regulatory criteria to fluoropolymers II: Fluoroplastics and fluoroelastomers, 2023).

II. Specific Uses of PFASs: Request for a Temporary Exemption for the Use of Specific Fluoropolymer PFASs in Data Communication Applications

There are several electronic components in the data communications sector that utilize PFASs. Polytetrafluoroethylene (“PTFE”), perfluoroalkoxy alkane (“PFA”), fluorinated ethylene



2225 W. Chandler Blvd | Chandler, AZ USA

propylene (“FEP”), and fluorinated surfactants are used in the manufacture of copper clad laminates (“CCL”), which are used to make printed circuit boards (“PCBs”). PCBs are used in diverse applications across a wide array of industries, including aerospace and defense, automotive, wireless communications infrastructure, digital (wired infrastructure), medical, and general industrial equipment. Fluorinated polymers are used as dielectric materials separating conductive copper layers in PCBs. Since PTFE materials are expensive to purchase and fabricate, they are only used when their performance attributes are absolutely essential. **These applications require superior electrical performance and exceptional stability and reliability in environments around the globe. There are no current alternative materials that have been demonstrated to have consistent electrical performance during high temperature excursions and long lifetimes.**

Key Functionalities provided by PFASs: Electronics – Printed Circuit Boards Used in Data Communications

The Annex XV Report acknowledges that PFASs are commonly used in the production process of electronic components. However, for these applications, it should be emphasized that specific PFASs (PTFE, PFA, FEP) are also the key material constituting the dielectric layer of the PCB itself. Due to their unique combination of properties, the PTFE, PFA, and/or FEP are the key enabling constituents of the performance required of such PCBs for mission-critical applications, including:

1. Low dielectric constant and low dissipation factor enabling superior electrical performance and reduced energy consumption of electric devices;
2. Stable electrical and mechanical properties over varying environmental conditions such as high humidity and temperatures above 130°C, enabling stable performance in all environments where data communication networks are needed; and
3. Inherently flame retardant.

As explained further below, PTFE, PFA and FEP are key constituents of the dielectric layer of PCBs are used in multiple data communications applications, such as 4G and 5G network base stations, antennas and power amplifiers, satellites, and consumer devices (e.g., tablets, cell phones, laptops, etc.).

Specific Use Application: 4G and 5G Base Station Antennas

A major area where PTFE-based circuit boards are used is in antenna products required for telecommunications. Many 4G and 5G base station antenna applications require a level of performance that only PTFE-based PCB boards can provide. One specific and essential property to ensure these antenna products meet the performance requirements is the reduction of passive intermodulation (“PIM”). This is a measure of signal interference that must be minimized to enable clear phone signals and to reduce loss of data (Coonrod, Choosing Circuit Materials for Low-PIM PCB Antennas, 2017). PIM is a serious issue for cellular operators wanting to maximize their



2225 W. Chandler Blvd | Chandler, AZ USA

network's reliability, data rates, and capacity. As cell usage and throughput grows, the peak power produced by digital modulators increases, contributing heavily to PIM (Anritsu America, 2023). The level of PIM which can cause a problem is at an incredibly low energy level. The acceptable level of PIM is mostly due to the sensitivity of the system. PIM is measured in units of dBc, which is the power level (dB) in relationship to the carrier signal (c) power (Coonrod, PCB-Based Antennas and PIM Concerns, 2016). A larger negative number is better, and -160 dBc is considered to be a good performance level for the system. For a reference example, field measurements show download speed decreased by 18% when PIM increased from -125 dBc to -105 dBc (isola, 2015). Low PIM gets increasingly more important when the footprint of the device decreases, and the same antenna is used for transmit and receive functions. The choice of PCB material can play a large part in the PIM performance of an antenna. The material must have a consistent dielectric constant ("Dk") across the area of the antenna PCB board (+/- 0.05), and a stable Dk with temperature (low thermal coefficient of Dk +/- 50 parts per million per °C). The low thermal coefficient of Dk ensures that the Dk will change a relatively small amount with temperature, so as not to change the antenna's resonant frequency as well as not to alter radiation patterns for the designed frequency range (Coonrod, Materials Make the Difference in Low-PIM PCB Antennas, 2016). In addition, the water absorption of the PCB antenna board should be low to maintain a stable Dk with humidity (isola, 2015). These material properties are required because printed antennas and their transceivers must perform flawlessly over a wide range of operating conditions, from day to day or from season to season in outdoor base stations and cell sites around the globe (Coonrod, Materials Make the Difference in Low-PIM PCB Antennas, 2016).

PTFE-based PCB materials are the only materials that consistently meet the PIM performance targets of the telecommunications industry. When non-PTFE alternatives are used, there are a higher level of field failures due to heat-induced breakdowns of the units and decreased performance due to the antenna detuning. The heating of the boards degrades performance further, as it increases the level of noise in the signal as the PIM performance is reduced. Alternatives are being actively developed, but are still likely more than 5 years away due to the unique combination of electrical and thermal properties required for a successful application.

PFASs Use Application: Power Amplifiers and Couplers

Two important components of a cell phone are the power amplifier ("PA") and the coupler. Wireless transmissions require modulated waves to be sent across long distances through the air. The signals are transmitted using antennas, usually as part of cellular networks, and the range of transmission depends on the magnitude of signal power to the antenna. Radio frequency ("RF") power amplifiers are used to increase the magnitude of the power to a level high enough to cross the required transmission distance (Teja, 2023). Cellular base station signal amplifiers repeat the original signal, after boosting it, which enhances the signal strength. A directional coupler in the system measures and controls the output power of the PA signal sent to an antenna (Ninknejad, 2014). This results in better cell phone reception, improved call quality, and increased data transfer speeds (Thornburn, The Science Behind Cellular Amplifiers Simplified, 2019). Even though cellular networks are often found in urban areas, there are remote and rural areas that do not have



2225 W. Chandler Blvd | Chandler, AZ USA

a large population of cellular towers. In addition, in city areas, cellular signals are often blocked by man-made objects such as skyscrapers, tunnels, and bridges. Even weather can influence and disrupt the signal, decreasing the signal strength (Thornburn, *The Science Behind Cellular Amplifiers Simplified*, 2019). To ensure adequate signal strength in all of these situations, power amplifiers are required.

As data rates and throughput of calls have increased, the amount of signal amplification has also increased, resulting in the need for greater power handling requirements of both PAs and couplers. To perform, the PA and coupler materials must have a low dissipation factor (“Df”) to minimize the amplified signal loss creating intrinsic heating, must have high thermal conductivity to handle the signal amplification without excessive extrinsic heating of the active component, and must be thermally stable to avoid material breakdown and prevent arcing during high voltage operation (Kang, Smith, & Frankosky, 2010). (Arcing is electronic discharge that can short or burn the PCB.) In addition to these criteria, the unit must work reliably after being mounted to a cellular tower outdoors with continuous environmental exposure. RF laminate materials based on PTFE are the only materials that meet all these criteria.

There are several materials from which RF laminates can be made currently. These include epoxy-based materials (including “FR-4”), several thermoset materials such as polybutadiene (“PBD”) or polyphenylene oxide (“PPO”), as well as PTFE. However, the thermal stability at increased temperatures remains the largest limitation of material type for the specific application of PAs and their couplers. The PAs can easily run at temperatures exceeding 100°C (Kang, Smith, & Frankosky, 2010), especially during summer months. FR-4 materials as well as current thermoset solutions can undergo thermo-oxidative breakdown at the elevated temperatures of operating PAs. Once the RF laminate material starts to degrade, arcing can occur which leads to burning of the boards. Only PTFE has been demonstrated as a field reliable material for this specific application. The PTFE is chosen over current alternatives, even at a higher price point, based purely on the performance requirements of the application, which cannot be met by the alternative materials.

Table 1. Comparison of RF laminate materials for key criteria for use as a power amplifier.

Material Solution	Dissipation Factor	Maximum Operating Temperature (°C)	Thermal Conductivity (W/mK)
FR-4 (epoxy)	0.01	90	0.4
Thermoset - PBD	0.004	90	0.6
Thermoset - PPO	0.002-0.004	100	0.6
Thermoplastic - PTFE	0.001-0.002	130 +	1.0 +



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III. Socioeconomic Impact to the EU

The electronic applications addressed herein are critical to achieve the EU Green Deal objectives. As part of the EU Green Deal, the EU has pledged for a 90% reduction in greenhouse gas emission in transport by 2050. This will be achieved by at least 30 million zero-emissions cars in operation by 2030. In addition, this mobility system has been pledged to be a ‘smart mobility’ system that uses the full potential of data to integrate electronic ticketing and paperless freight transactions. In addition, automated mobility is targeted for deployment on a large scale by 2030 (Communication, Directorate-General for, 2023). Beyond mobility, the EU Green Deal has the goal for a new Industrial Strategy for a globally competitive, green, and digital Europe. The pledge is for European industry to be greener, more circular, and more digital while remaining globally competitive (Directorate-General for Communication, 2023).

PFAS-containing components are critical to achieving these targets in mobility and digitization. PTFE-based circuit boards are used in embedded automotive electronics, enabling the safety and communication features required to increase mobility. The same type of circuit board materials are also the enabling materials that will allow for smart mobility, and execution on vehicle-to-vehicle and vehicle-to-grid communications that are robust across all driving conditions. For digitization, PTFE-based circuit board materials are essential in enabling 5G data transfer speeds. These materials are used in cell phones, laptops, tablets, and the public infrastructure. This higher speed of data transfer is necessary to make the EU a world leader for fully automated and connected mobility systems, as outlined in the European Commission’s Digital Strategy (Directorate-General for Communication, 2023).

According to market reports, the current European electrical market size is estimated to reach €335 billion by 2027. This market space covers industrial manufacturing, automotive, healthcare, and aviation, to name a few (Europe Electrical Components Industry Outlook - Forecast (2022-2027), 2022). This industry has a direct impact of €3.8 trillion, which is approximately 20% of European GDP (Mitchell, 2021).

For each application, development of an alternative would require significant investment in time (minimum of 5 years), materials (alternative resins are not currently commercially available), and cost to replace (€1.5M per application to develop an alternative and a minimum of €250 per customer per application to qualify). In addition, it is very unlikely that a ‘one size fits all solution’ will be identified as a PTFE-replacement, as it is a very unique material and used in a variety of electronic applications. The authors, along with the rest of the PCB industry, have been evaluating PTFE alternatives for over 30 years and have not found suitable replacement products meeting all the requisite application needs. Although there are other dielectric thermosetting materials meeting the performance requirements of many PCB applications, PTFE is required for the most demanding applications described herein. It is highly uncertain that replacement materials can be developed or found for these applications if PFAS (in this specific case PTFE, PFA, and FEP) are banned from use in electronic applications.



2225 W. Chandler Blvd | Chandler, AZ USA

The situation is different for PFAS-containing data communications devices that are already installed and in use. A ban on PTFE, PFA, and FEP would eliminate the availability for spare parts for currently installed units. There is currently a legal requirement that base station antenna systems be maintained for a specific length of time after installation. This amount of time varies depending on the country of installation. Drop in spare parts must be available for network providers to meet this requirement. Any change to the chemistry of the PCB would also change the required design and likely the physical dimensions of the component. This change would prohibit a ‘drop in’ approach. The current regulatory requirement to maintain active units necessitates an extended derogation request of 12 years, to cover the longest maintenance time regulated.

IV. Comment on Annex XV Report Derogations

For the electronic applications described herein, no derogations currently proposed in the Annex XV Report would apply. This is untenable, as alternative materials are not currently available for these applications.

Therefore, we request:

- I. The exclusion of the following fluoropolymers from the proposed restrictions of the Annex XV Report on PFASs:**
 1. polytetrafluoroethylene (“PTFE”) CAS # 9002-8-0 (CF₂CF₂)_n;
 2. perfluoroalkoxy alkane (“PFA”) CAS # 26655-00-5 (CF₂CF₂)_n-(CF₂CF(OCF₃))_m;
 - and
 3. fluorinated ethylene propylene (“FEP”) CAS # 25067-11-2 (CF₂CF₂)_n-(CF₂CF(CF₃))_m

As a result of their very high molecular weight, generally over 100 kg/mol, fluoropolymers have unique properties that distinguish them from all other PFASs. Fluoropolymers have a low impact to human health and the environment, as further detailed in this white paper. Thus, grouping fluoropolymers together with all other classes of PFASs for a single approach structure-hazard assessment based on persistence alone is not scientifically appropriate.

II. A temporary exemption for use of specific fluoropolymer PFASs in data communication electronic applications

We request that the proposed restrictions on PFASs provide a temporary exemption of at least 12 years for “data communication electronic applications”, specifically base station antennas, power amplifiers, and couplers, for:

1. polytetrafluoroethylene (“PTFE”) CAS # 9002-8-0 (CF₂CF₂)_n;



2225 W. Chandler Blvd | Chandler, AZ USA

2. perfluoroalkoxy alkane (“PFA”) CAS # 26655-00-5 $(\text{CF}_2\text{CF}_2)_n-(\text{CF}_2\text{CF}(\text{OCF}_3))_m$; and
3. fluorinated ethylene propylene (“FEP”) CAS # 25067-11-2 $(\text{CF}_2\text{CF}_2)_n-(\text{CF}_2\text{CF}(\text{CF}_3))_m$

PFASs, and in particular the fluoropolymers listed above, are critical to a broad array of electronic and communication components used in the data communication industry due to a unique combination of the following properties:

- a) Low dielectric constant and low dissipation factor enabling superior electrical performance and reduced energy consumption of electronics;
- b) Stable electrical and mechanical properties over varying environmental conditions such as high humidity and temperatures above 130°C, enabling stable performance in all environments where data communications networks are needed; and
- c) Inherently flame retardant.

Due to this unique *combination* of properties, PTFE, PFA, and FEP are extremely difficult to substitute in specific data communications components without significant tradeoffs in performance and lifetime, as there are no known alternatives that meet all of these performance criteria.

Significant invention is required to identify, and then qualify, each specific PFAS-free solution and there is no guarantee that this will be successful and on what timeframe. To date, no other class of materials has been able to demonstrate the collective performance benefits of PTFE, PFA, or FEP, as stated above. Typical qualification and test cycles for data communications applications are in the two-to-three-year range. This is after a new solution is invented and formulated to fit the form factor required by current data communications designs.

The situation is different for PFAS-containing data communications devices that are already installed and in use. There is currently a legal requirement that base station antenna systems be maintained for a specific length of time after installation. This amount of time varies depending on the country of installation. Drop in spare parts must be available for network providers to meet this requirement. This obligation necessitates the extended derogation request, to cover the longest maintenance time regulated, to avoid interruption that could have significant impact to critical communication needs.



2225 W. Chandler Blvd | Chandler, AZ USA

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2225 W. Chandler Blvd | Chandler, AZ USA

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2225 W. Chandler Blvd | Chandler, AZ USA

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