W. L. Gore & Associates’ Comments on Dossier Submitters’ Draft EU REACH restriction on PFAS

Public consultation

Request for Derogation:
Ingress Protection Vents for Communication Devices

June 2023

Gore appreciates the opportunity offered by the public consultation process to provide comments on the Proposal for a Restriction of Per- and polyfluoroalkyl substances (PFAS) (hereinafter **'Restriction Proposal'**).

We would like to propose that a 13.5 year derogation for **vents for ingress protection in devices used for communications** (e.g. smartphones, emergency responder 2-way radios, and wearable devices such as wireless headphones, smart watches, etc.) is needed and justified. This application is not covered by the derogations currently proposed and some of the uses are not mentioned in the Restriction Proposal. It would be beneficial to include in the Restriction Proposal a discussion on the availability of alternatives for ingress protection in communications devices, along with a more in-depth review of the lack of availability of alternatives for this application.

The conclusions from our statement are summarized as follows:

- **Protecting communications devices from failure due to liquid or dust ingress is a critical function** for hundreds of millions of EU citizens in personal, professional, and emergency settings. Increasing the longevity of such devices is also an important factor in reducing electronic waste and the consumption of critical raw materials.
- Currently, **no alternative is available** that would prevent device failure and that would not require PFAS chemistry.
- If suitable alternative materials are identified as a result of ongoing research, it would take several additional years to develop, test and produce devices that can incorporate the alternative materials.
- Without a derogation, there would be a significant increase in the failure rate of these devices which both the general population and professionals rely on for their daily and urgent communications. This would result in an increase in waste and resource consumption. For example, consumers could face an additional cost of more than €600 per device to replace a damaged device, which at an EU level amounts to a cost of more than €16 billion per year. Additionally, more than 5 million kg of electronics waste would need to be managed. These costs are not justified given the exceptionally low volume of PFAS required for this end use annually in the EU (< 30 kg).

I. Derogation Request

Considering the arguments and evidence presented below as well as previously submitted evidence, Gore respectfully requests to include the following application-specific derogation in Column 2, paragraph 5 of the proposed restriction:

Ingress protection[1] vents for devices used for communications until 13.5 years after EiF;

[1] Ingress protection is the protection against external contaminants either liquid (e.g. water, oil) or solid (dust)

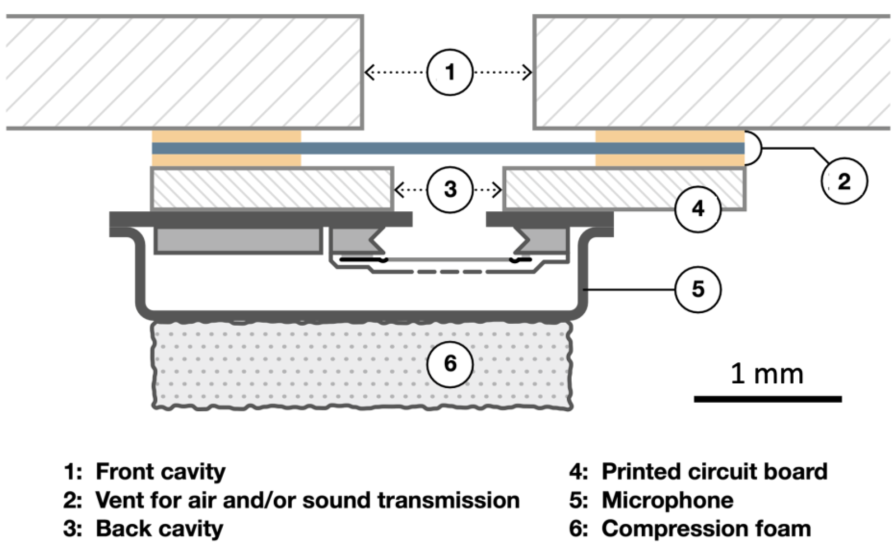
II. Description of the End Use

Devices used for communications, which includes smartphones, 2-way radios and wearable electronic devices, like smart watches and wireless headphones, have become a part of everyday life for citizens in Europe and critical for use in emergencies. In 2022, approximately 150 million smartphones and 80 million wearable devices were sold in the EU[2]. These devices must have openings to the environment to allow for pressure equalization, the transmission of acoustic signals to and from microphones and speakers, and to enable sensors to collect environmental data like air and water pressure. Users expect that their device will not be damaged or destroyed if it falls into water, is exposed to rain, or is cleaned.

Due to the sensitive nature of the electronics (microphones, speakers, sensors, circuits) in these devices, they can be easily damaged by particulates, water, oils, cleaners, and other contamination. To overcome this issue, device manufacturers provide ingress protection by using a PFAS based microporous vent. The protection helps eliminate component failures, extends the life of the device, and reduces the environmental waste from prematurely replaced devices. These vents contain an extremely low mass of PFAS and are often only 4mm in diameter and weigh approximately 30 µg. Without effective protection against external contaminants such as liquids and particulates, the device will fail and must be replaced.

The below diagram illustrates how a vent for air and/or sound transmission is assembled into a typical smartphone. Although based on a Gore product, this diagram is representative of products manufactured and placed on the EU market by other companies.

Figure 1. Ingress protection vent for air and/or sound transmission in a typical smartphone



[2] International Data Corporation (IDC), https://www.idc.com/prodserv/insights/manufacturing/latest-research

III. Reference in Restriction Proposal

The Dossier Submitters (DSs) researched the electronics applications of PFAS in detail (as presented in Annex A Table A.1, page 5) and the use of polytetrafluoroethylene (PTFE) is listed in the context of sound-permeable membrane (Restriction Proposal Annex A, Table A.48, page 107). The properties required and provided by PTFE are acknowledged (air permeability, water pressure resistance, liquid repellence, and acoustics characteristics).

However, in Annex E of the Restriction Proposal where the derogation and availability of alternatives are discussed, the Dossier Submitters did not assess the need for PFAS in these applications. In the analysis of alternatives, the applications described in this document fall within the succinct statement by the DSs that considering “the inconclusive evidence pointing to the non-existence of technically and economically feasible alternatives at EiF in all other uses, no derogation is proposed” (Annex E, Table E.131, page 404). The applications described in this document do not appear to have been included in the DS analysis of alternatives for electronics. Considering the broad variety of applications of PFAS in electronics and that the DSs chose to discuss together alternatives covering electronics, semiconductors and even energy sectors (Annex E, section E.2.11.2. from page 389), it remains unclear which alternatives have been considered for PFAS in ingress protection vents.

In this document, we provide evidence that there are no currently available technically and economically feasible alternatives for these applications, and therefore a derogation is warranted.

IV. Need and Justification for Derogation

Without a derogation, communications devices which both the general population and professionals (emergency services, transport operators, etc.) rely on for their daily and urgent communications would have a much higher failure rate due to water and dust contamination, leading to more resource consumption and waste. We propose that a derogation is justified based on the following points:

- The **performance requirements** for ingress protection in devices used for communications.
- The **lack of availability of alternatives** that would provide the required level of performance.
- The **time required** for research and development to investigate and evaluate potential alternative materials, and if a feasible alternative is identified, the time required to identify develop, test, and commercialize a new vent in a device.
- The **extremely low volume of PFAS** needed for this application in comparison to the **large socio-economic cost** of restricting the use.

1. Performance Requirements for Ingress Protection Vents

Ingress protection vents for communication devices have a wide range of unique and technically demanding requirements. The primary challenge is providing ingress protection whilst enabling adequate airflow.

a. Hydrophobicity and Oleophobicity - Barrier to water and other liquids

The material needs to be hydrophobic, enabling the membrane to repel water and, in some cases, oleophobic which enables it to repel an even greater range of fluids. The ability to repel substances is dependent on surface energy. Surface energy is a typical material property used to characterize hydrophobicity and oleophobicity.

At the device level, a common standard used for communications devices is the Ingress Protection rating (or IP rating), which is an international standard (IEC 60529) used to rate the degree of protection or sealing effectiveness in electrical enclosures against intrusion of objects, water, dust, or accidental contact. It corresponds to the European standard EN 60529. A summary of the rating system is shown in the table below.

Table 1. Ingress Protection (IP) standards[3]:

Ingress Protection Rating Format: IP X Y

Protection Against Foreign Solid Object (X)		Protection Against Liquid (Y)	
0	No protection	0	No protection
1	Protection against solid objects > 50 mm, such as a hand	1	Protection against vertically dripping water, some ingress permitted
2	Protection against solid objects > 12.5 mm, such as a finger	2	Protection against dripping water with enclosure tilted up to a 15° angle
3	Protection against solid objects > 2.5 mm, such as tools	3	Protection against spraying water
4	Protection against solid objects > 1.0 mm, such as wire or small screws	4	Protection against splashing water
5	Dust resistant, limited protection from the ingress of dust, ingress of dust not sufficient to cause harm	5	Protection against jets of water directed at the enclosure
6	Dust-tight, total protection from the ingress of dust	6	Protection against powerful jets of water directed at the enclosure
		7	Protection against submission or exposure to water up to 1 m for a period of 30 minutes
		8	Continuous immersion in more than 1 meter of water for 30 minutes in test conditions subject to agreement between manufacturer and user.
		9k	Protection against high pressure and temperature water jet

[3] IEC Standard 60529 “Degrees of protection provided by enclosures”. Version 60529:1989+AMD1:1999+AMD2013 CSV Consolidated Version

For example, IP 68 means a total protection from the ingress of dust and continuous immersion in more than 1 meter of water for 30 minutes in test conditions agreed on between a manufacturer and user, meaning a device with an IP68 rating may be designed to withstand 3 meter immersion or 6 meter immersion. Meeting this rating is critical for everyday and emergency performance.

In addition to IP rating, there are more challenging requirements placed on communications devices that protect from conditions that arise in common use cases. For example, devices must often retain their immersion protection after coming in contact with soapy water, as might happen when a smart phone is cleaned or dropped in a sink or when a smartwatch is worn during hand washing. This requirement puts more stringent contamination resistance requirements on vents to prevent premature device failure. Soapy water is just one of many potential low surface tension fluids that may challenge vents in this application, all of which are more likely to cause ingress and potential device failure than a pure water challenge.

b. Microporous Structure - Good Sound Transmission and Ability to Equalize Pressure

The immersion protection capability of a membrane against ingress of liquids or particulates is determined by multiple factors of which porosity has a large impact. Large pores allow more ingress than small ones. At its extreme, the ultimate immersion protection material is full density, non-porous barrier (e.g. having no opening, a sheet of metal) which allow no liquid ingress. However, this approach does not provide the needed breathability or acoustic properties to function as a vent on a communication device.

The membranes which are used in these vents for air and/or sound transmission need to be a thin and low-mass membrane with mechanical properties and a porous microstructure that enable optimal transmission of air and/or sound. In some cases, the membrane vibrates easily and quickly in response to sound waves, converting their airborne energy to mechanical vibrations. These vibrations are reproduced on the other side of the membrane to create high-quality acoustics. In other cases, the vent microstructure is permeable enough to allow direct transmission of the sound waves through the membrane's porosity.

The optimized permeation properties enable the vent structure to rapidly equalize pressure changes due to temperature increases or decreases or air pressure differences as they may occur, e. g., during air transport. The vent also protects sensitive electronics against condensation and minimizes stress on device seals.

c. Thermal Stability

Some ingress protection vents must also survive the extremely high temperatures (250°C) associated with the soldering processes used for device assembly. While the device shown in Figure 1 shows an ingress protection vent that is attached to the outer casing of a device, some applications for ingress protection for communication devices require the vent to be integrated into an individual electrical component (e.g. integrated into the microphone or sensor). This approach allows for more robust device designs, removes potential leak points in adhesive seals to the outer casing, and can thereby further reduce the risk of device failure due to water ingress. But integrating the ingress protection vent into the electrical component requires that the ingress protection material can survive temperatures associate with solder reflow, a process used to attach the electrical component to a circuit board. This solder reflow process often uses temperature in excess of 250°C.

2. Assessment of Alternatives

a. Why Fluoropolymers and other PFAS can uniquely deliver the needed performance

Today, only PFAS based vents can meet the combination of highly demanding requirements. Polytetrafluoroethlene (PTFE) is the primary material used for vents in communications devices. Additional fluoropolymers and other PFAS listed below in Table 2 are used to construct the finished vent article and provide an enhanced oleophobic surface on the PTFE membrane so that it more effectively repels oils, sweat, cleaning solutions, and other common fluids that can threaten device reliability.

i. Microporous structure

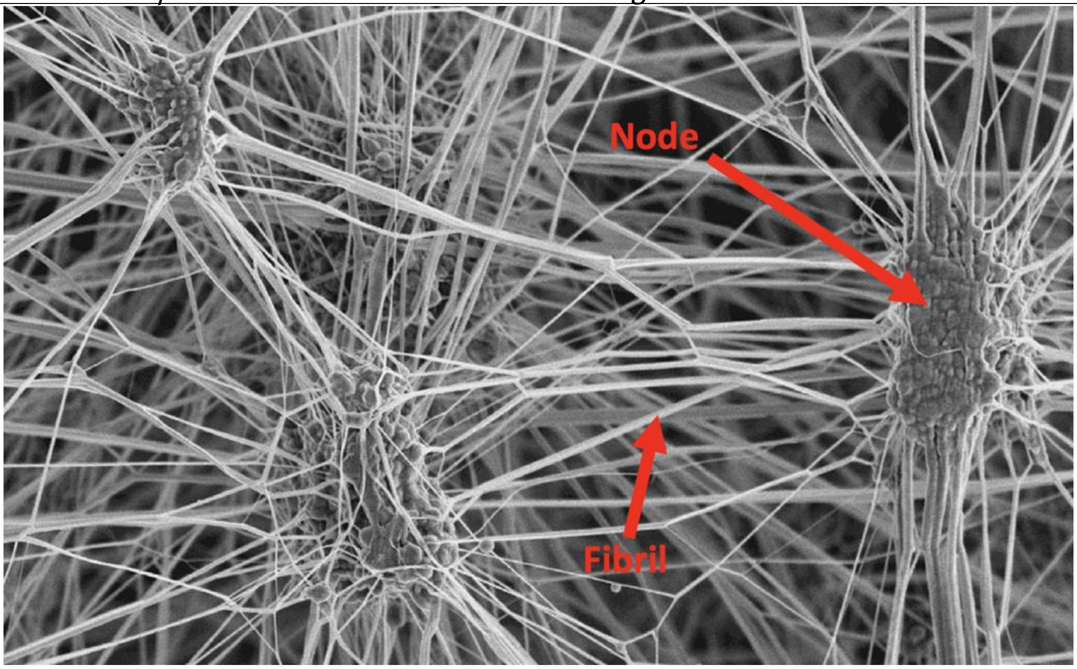
PTFE is the only known material that has the inherent physical properties which make it suitable and can also be expanded into a thin, strong microporous membrane to deliver additional characteristics necessary for this end use.

Its microstructure facilitates the transmission of air and sound, while effectively repelling water, other fluids and particulates. **It is the unique combination of the properties listed below which have not been identified in any other alternative materials that have been investigated by Gore and other companies to date.**

The PTFE membrane is engineered with a porous microstructure that enables optimal transmission of air and/or sound. The thinness and specific pore size allows sufficient acoustic transmission.

The transmission properties of the expanded PTFE (ePTFE) membrane also enable the vent structure to be air permeable to rapidly equalize pressure changes, protecting sensitive electronics against condensation and minimizing stress on device seals. The combination of small pore size and hydrophobicity enable resistance to wetting with water. The image in Figure 2 shows the complex microscopic pores providing this combination of properties. For a sense of scale, a very fine human hair (30 microns in diameter) would cover the entire field of view in this image.

Figure 2: Example of ePTFE Microstructure Showing the Node and Fibril Microstructure



The image above shows a "node and fibril" microstructure which is characteristic of an expanded PTFE membrane. "Fibrils" are the thin fibers, and "nodes" are the solid regions to which the fibrils are connected.

Very few polymers can be processed into microporous structures, and the process used for producing PTFE membranes[4], known as "paste processing and expansion", is particularly well-suited to creating a wide range of microstructures and thicknesses of membranes not typical of other membrane fabrication processes.

The resulting membrane properties depend on many factors, including the starting polymer properties, the temperature at which the membrane is expanded, and the amount of stretching that is applied during the expansion process. The wide range of process space allows for a wide array of membranes to be manufactured through this process. One key attribute of PTFE is that it has a very wide range of temperatures over which it can be stretched (from around room temperature up to in excess of 300°C). The expansion process converts the fine powder resin into "fibrils", and polymer that is not converted into fibrils remains in "nodes", resulting in expanded PTFE's characteristic node and fibril structure. The node and fibril microstructure of expanded PTFE is well-known[5] to offer a unique combination of air permeability, water resistance, mechanical strength, and acoustic transmission.

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[4] This process, known as paste-processing, was first described in US Patent 3,953,566, assigned to W. L. Gore and associates. The process is also outlined with some detail in "Expanded PTFE Applications Handbook: Technology, Manufacturing and Applications" by Sina Ebnesajjad.

[5] US Patent 6512834B1 "Acoustic protective cover assembly", W. L. Gore and Associates

The membrane can optionally be laminated with other support materials, coated, or otherwise treated to impart additional properties. For example, the membrane can be treated with additional PFAS in the form of a coating or surface treatment to increase its oleophobicity and contamination resistance, further adding to the unique combination of material properties of the PTFE membrane.

PTFE is the only polymer that can be commercially processed using the above-described process. Extensive research and development by Gore and other leading manufacturers has not identified any other polymer material which:

- is compatible with paste processing
- can be expanded to produce a microporous membrane
- is available in the fine powder form required for paste processing
- has a wide processing temperature range

Therefore, there are no known alternative membranes with this characteristic microstructure.

ii. Hydrophobicity

Hydrophobicity is the ability of a solid material to resist the spreading of water on its surface. Hydrophobicity is a key property for a material which is used to manufacture a membrane to provide ingress protection of communication devices. Membranes made from hydrophobic polymers resist wetting with water and thereby prevent water entry into devices which can cause failure. The greater the hydrophobicity, the better a membrane can resist wetting. The less hydrophobic a material is, the more likely it is that it will fail to resist wetting with water and lead to device failure.

Surface energy is a fundamental measure of hydrophobicity. The lower the surface energy, the more hydrophobic a material is.

Expanded PTFE is naturally hydrophobic and has a surface energy of 19 dynes/cm. This allows it to easily repel fluids with surface tensions above 40 dyne/cm, such as water (72 dynes/cm) and coffee (40 dyne/cm). When treated with an additional fluoropolymer, the surface energy can be further decreased.

Not all polymers are hydrophobic, and no other polymer as inherently hydrophobic as PTFE can be processed into as broad an array of microstructures as PTFE.

An extension of hydrophobicity is oleophobicity, which requires even lower surface energy, and enables non-wetting properties with lower surface tension fluids and will be discussed later.

iii. Oleophobicity/Contamination Resistance

Oleophobic treated PTFE has a reduced surface energy and can effectively repel fluids with very low surface tensions.

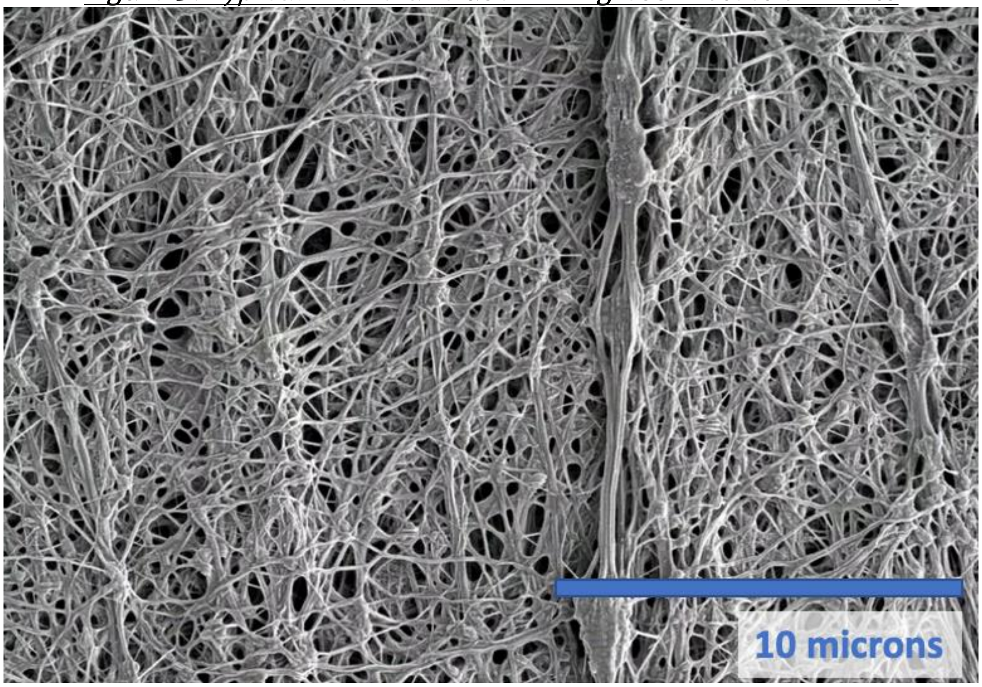
For example, the surface tension of household cleaners range from 27–32 dynes/cm, and the surface tension of isopropanol is 22 dynes/cm. If these fluids were to penetrate through a vent during cleaning, they could cause catastrophic damage to electronic components. In the later section detailing alternatives assessment, we will provide specific data that shows that the presence of an oleophobic treatment on a PTFE membrane enables durable water resistance after a vent is exposed to soapy water. Without this treatment, exposure of a communication device to soapy water (e.g. cleaning a device, dropping a cell phone in a sink or vigorously washing one's hands while wearing a smartwatch) could significantly degrade its immersion protection, leading to device failure.

In addition to reducing the ingress of liquids, the oleophobic properties of treated PTFE reduce the wettability of the acoustic vent membrane, so that liquids do not remain on the membrane and degrade acoustic performance or risk clogging the microstructure.

iv. Achieve IP68 Standards

Although the expanded PTFE membrane is extremely thin, its unique structure is engineered to effectively repel debris, water, and other fluids. It also provides ingress protection up to IP68 standards which represents complete protection from particles and at least 1 meter immersion protection (at a level that is specified by the manufacturer). The membrane has a complex, three-dimensional microstructure which provides a tortuous path through the material. This complex, tortuous path traps very small particles with high efficiency creating an effective barrier to particles of varied sizes. The image below is a scanning electron micrograph of a membrane used for ingress protection for communication devices. The pores in this microstructure are considerably smaller than one micron in diameter, and their complex geometry ensure capture of small particles.

Figure 3. Typical Membrane used in Ingress Protection Vents



In addition to having the appropriate microstructure, the membranes must have sufficient strength to survive the mechanical challenge associated with pressurization. For example, if a membrane is used to protect a device from immersion in 6 meters of water, the water will apply a pressure of 60 kilopascals to the surface of the membrane when under challenge. Under this applied pressure, the membrane must not break or significantly deform in a way that would allow water to enter and damage components, thus causing device failure.

v. Thermal stability

Many ingress vents must also survive the soldering processes used for device assembly and cope with high temperatures (≥250°C).

PTFE is a very thermally stable polymer, only melting at temperatures well above 300°C, allowing its use in such conditions. Most other polymers that can be made into porous materials cannot survive such temperatures. For example, porous membranes can be made from polyethylene, polyurethane, nylon, and polysulfone but all of these polymers start degrading well below 250°C. Two thermally stable polymers that can be made into porous membranes are PEEK (polyether ether ketone) and PI (polyimide). However, they have considerably higher surface energy than PTFE (42 dynes/cm[6] and 44 dynes/cm[7]), and therefore do not have the required hydrophobicity and oleophobicity properties. They are also not compatible with the process used to make PTFE membranes, so they do not offer the

[6] http://www.surface-tension.de/solid-surface-energy.htm, accessed 5/22/2023

[7] https://ntrs.nasa.gov/api/citations/20090026494/downloads/20090026494.pdf, accessed 5/22/2023

characteristic node and fibril microstructure known to be associated with strong performance in this application.

There are no polymers available today that can survive the high temperatures experienced during the component soldering process and can also be engineered to provide microstructure, hydrophobicity, and oleophobicity of a PTFE membrane with an oleophobic treatment. PFAS-based treatments that can be applied to PTFE also can survive such temperatures.

vi. Typical Materials

In terms of PFAS content and using Gore vents as an example, these products are mainly made of fluoropolymers (PTFE, PFA) with other additional PFAS. The majority of the components meet the criteria for Polymers of Low Concern (PLCs), under the definition provided by the OECD Expert Group on Polymers. The materials used are shown in Table 2.

Table 2. Typical PFAS Materials used in Ingress Protection Vents

Type of PFAS	Function of PFAS	Fraction of PFAS content	CAS number	Is this PFAS a PLC?
PTFE	[redacted]	[redacted]	9002-84-0	Yes
PFA	[redacted]	[redacted]	26655-00-5	Yes
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

b. Alternatives Listed in Restriction Proposal

The Dossier submitters identified several materials as potential alternatives for PFAS applications in electronics and semiconductors (Annex E, table E.128, page 396). Not all these materials are relevant to ingress protection for communication devices. We will only discuss technologies which are relevant to the application referenced in this submission.

None of the alternatives mentioned by the Dossier Submitters in the restriction proposal in reference to the broad category of electronics are suitable for protection of devices used for communications. No alternatives are available that would prevent device failure and that would not require PFAS chemistry at all. Alternatives may be able to replace a singular property, but when two or more properties are required simultaneously in communication devices. Thus, the only currently viable material is a composite article made from fluoropolymers and other PFAS.

i. Non-porous covers (urethane, silicone, PEEK)

Non-porous covers such as urethane, silicone or PEEK can be used to cover apertures when immersion protection is needed with satisfactory sound transmission. However, these materials do not breathe and do not allow for pressure equalization, which is required to alleviate pressure changes that may arise due to typical use (e.g. going up in an elevator or airplane or due to temperature changes), and may in turn also degrade sound transmission. If pressure is not equalized, it will build, applying undue forces to the membrane, device seals, and every other internal component. Such forces will destroy the membrane, break seals, and damage components that are critical to the function and continued survival of the device. **Therefore, non-porous covers are not a viable alternative for ingress protection vents.**

ii. Woven mesh covers

Woven mesh covers can protect an aperture from liquid splash, light spray or rain. However, any dust particles smaller than the defined hole size will pass through as these mesh covers because they consist of a single-layer grid and spacing pattern with a defined hole size. Moreover, this alternative will not protect against immersion or aggressive spray. A device which is not robustly protected can allow ingress of dust, which can degrade or induce failure in sensitive components like microphones. A device without protection from immersion is subject to water ingress, which can lead to total device failure. **Therefore, woven mesh covers are not a viable alternative for ingress protection vents.**

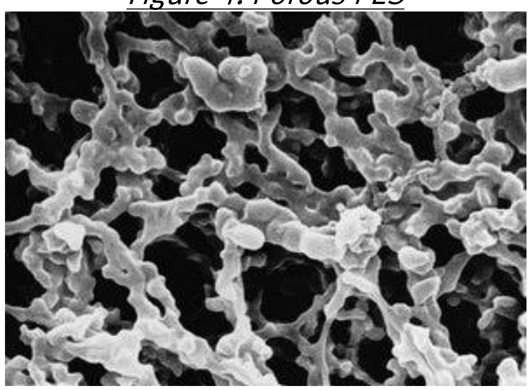
iii. Alternate porous membrane

A variety of non-PFAS polymers can be used to fabricate porous membranes, but these other materials do not have sufficiently low surface energy and cannot be processed to yield the characteristic node and fibril microstructure of expanded PTFE associated with suitable applicability in ingress protection vents for communication devices. These non-PFAS polymers **are not water repellent, so are not a viable alternative for ingress protection vents.**

There are several processes that can be used to produce porous membranes from non-PFAS materials. Phase inversion processing is a type of process for making porous membranes by transforming a polymer solution into a solid state in a controlled manner. Electrospinning is a process that uses high voltage to spin fibers from polymer solutions. Track etching is a process that uses nuclear tracks to create pores in polymer films. Sintering is process of fusing particles of polymer into membranes. The diagrams below show representative examples of membranes made through each of these processes. In each case, it is obvious that the membranes have different microstructures than what is shown in Figure 2.

Phase inverted membranes have no presence of node and fibril microstructure. An example of such a membrane is a Polysufone (PES) membrane[8], shown below. **Polysufone is not water repellent - it has surface energy of 47 dynes/cm, which is much too high for use as an ingress protection vent.**

Figure 4. Porous PES

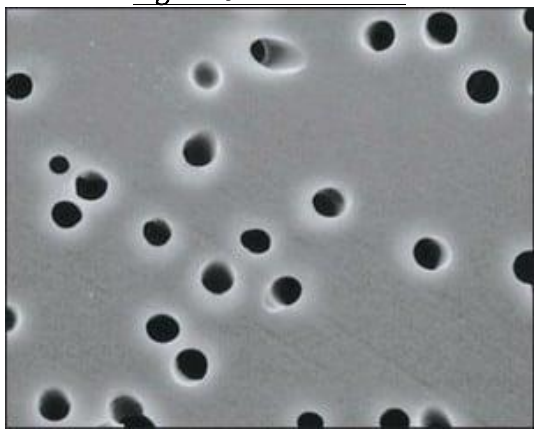


Track etched membranes do not have a node and fibril structure. An example of this technology, a track etched PET membrane[9], is shown below. **PET is not water repellent - it has a surface energy of 39 dynes/cm, which is too high for use as an ingress protection vent. In addition, these membranes are of low porosity, and offer poor permeability.**

[8] https://www.sigmaaldrich.com/US/en/product/mm/gpwp04700, accessed 5/23/2023

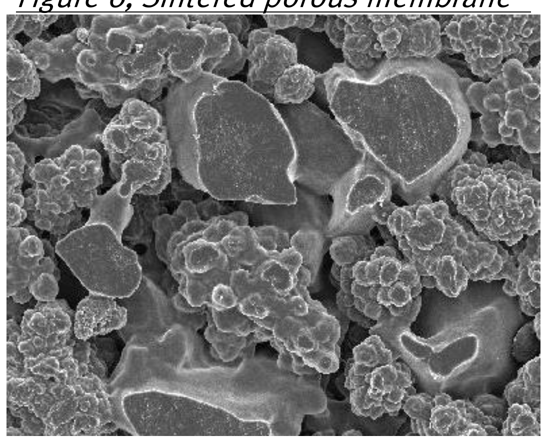
[9] https://www.sterlitech.com/blog/post/etching-the-tracks-in-a-polycarbonate-track-etched-membrane-filter, accessed 5/22/2023.

Figure 5. Porous PET



Sintered polymer membranes do not have a node and fibril microstructure. An example of this type of membrane, a sintered polymer membrane, is shown in the diagram below. **These membranes have a low porosity and are relatively thick. Furthermore, the sintered polymer membranes are not sufficiently water repellent and are not a viable alternative for ingress protection vents.**

Figure 6, Sintered porous membrane[10]



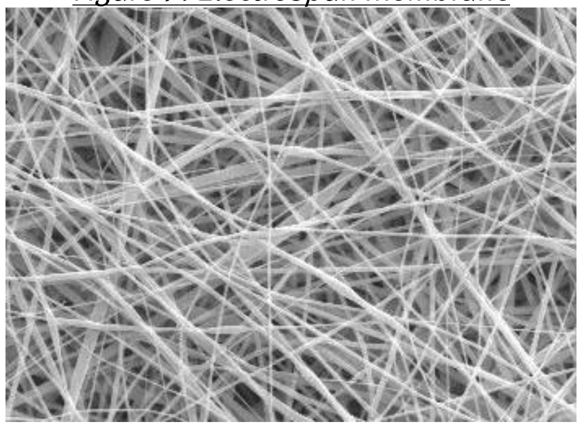
Electrospun membranes are comprised of extremely long fibers, which do not have connection points at nodes like in a node and fibril microstructure, as can be seen in the diagram below[11]. Such membranes are also typically characterized by having low cohesive strength. **Electrospun membranes offer some features that may be useful for venting applications for communication devices, but are either comprised of polymers which are not water repellent because they have high surface energy (e.g. polyurethane, nylon) or they are fluoropolymers (e.g. PVDF).** One

[10] https://www.porex.com/porous-polymers-technology/, accessed 5/22/2023.

[11] http://electrospintech.com/generalcharacteristics.html#.ZGu7EuzMLfs, accessed 5/22/2023.

electrospun membrane has been characterized more completely as will be described in the following section.

Figure 7. Electrospun Membrane



iv. Polyethylene (PE) and polyurethane (PU)

Two potential membrane technologies which appeared to have some level of hydrophobicity and well-established manufacturability are expanded polyethylene (PE) and electrospun polyurethane (PU). These were selected by Gore for more thorough evaluation as their property profiles indicated they may possibly be potential candidate alternative materials. As shown in Table 3, samples having pore sizes similar to current PFAS vent solutions were selected.

Table 1 : Membranes Selected for Contamination Resistance Study

Sample Type	Pore Size [microns] [12]
Commercial ePTFE + PFAS Coating	0.50
Commercial ePTFE	0.61
ePE Reference #1	0.69
ePE Reference #2	0.43
Electrospun Polyurethane Reference	0.43

These membranes were evaluated for their immersion protection properties when subjected to industry qualification methods which model typical mobile device consumer behavior. As highlighted above, an ingress protection level of IP68 means total protection from the ingress of dust and continuous immersion in more than 1 meter of water (in agreement with the manufacturer and user) for 30 minutes. In this case, the immersion depth that is relevant for these materials is 6 meters, so that was the depth at which testing was performed.

[12] Pore sizes of these membranes were determined via a bubble point measurement on a Quantachrome 3GzH capillary flow porometer, in accordance with ASTM F316-03.

Error! Reference source not found. shows survival probability in a water submersion test after exposure[13] to soapy[14] water for each membrane material, which is a typical qualification method for communication devices. After exposure to 0.01% soap in water (ten times less concentrated than a standard solution), all candidate alternative materials (ePE and electrospun polyurethane) as well as uncoated ePTFE exhibit a failure rate of 50% or greater.

All alternative materials and uncoated expanded ePTFE exhibit a survival probability near 0% after exposure to a standard soapy water solution of 0.1% soap in water. In contrast, more than 80% of samples made of ePTFE with an additional PFAS coating pass the submersion test after exposure to 0.1% soapy water.

Table 2 : 6 meter water submersion survival probability

Sample Type	**0.01% Soap/Water**	**0.1% Soap/Water**
Commercial ePTFE + PFAS Coating	> 80%	> 80%
Commercial ePTFE	< 30%	~ 0%
ePE Reference #1	< 20%	~ 0%
ePE Reference #2	< 40%	~ 0%
Electrospun Polyurethane Reference	~ 50%	~ 0%

Despite having comparable pore size to fluoropolymer-based membranes, PE and PU did not show sufficient resistance to wetting after exposure to soapy water.

Only the expanded PTFE membrane with PFAS coating showed acceptable survival in the water immersion challenge after a typical soapy water exposure. This is attributable to its low surface energy, which is a unique property of PFAS materials. Polyethylene has a surface energy of 30 dynes/cm, polyurethane has a surface energy of 38 dynes/cm, while PTFE has a surface energy of 19 dynes/cm.

PE and PU also do not offer thermal stability comparable to PTFE, which does not melt until temperatures in excess of 300°C. Ultra-high molecular weight PE, the most thermally stable grade of PE, melts at approximately 150°C, at which point structure and other properties will

[13] Samples of these flat sheet membranes with a diameter of 1.5mm were prepared, and small droplets of soapy water (20 microliters in volume) were placed on the surface of the parts. Soap solutions were prepared in a range of concentrations (e.g. 0.01% v/v, 0.1% v/v, 1% v/v). The samples were dried in an oven at 60°C for three hours until completely dry. Once dry, samples were pressurized with clean water on the soapy membrane surface at a pressure equivalent to submersion in 6 meters of water (0.6 bar) 13. If water was passed through the membrane, the time was noted, and the test was marked as a failure.

[14] The soap is a mixture of sodium lauryl sulfate (SDS or SLS), lauramine oxide (LO), sodium chloride (NaCl), and water. The ratio of SLS:LO:Salt is 5:2:3, and the mixture is 80% water by mass.

degrade considerably. Thermal degradation of PU can also begin at temperatures as low as 150°C[15].

So, while membranes made with these potential alternative materials have some properties similar to PTFE membranes, their level of performance in testing shows that they are not suitable alternatives in their current forms due to fundamental material properties inherent to their chemistry. **Therefore, Polyethylene (PE) and polyurethane (PU) membranes are not viable alternatives for ingress protection vents.**

v. Other Design Approaches

Alternative design approaches which have been considered are shown below, however **they do not provide ingress protection, and are therefore not viable alternatives.**

Table 5. Alternative Design Approaches

Alternative Technologies/Design: As the DSs focus mainly on alternative materials, we would like to complement the alternative discussion and present options that require an alternative technology/design.	**Open apertures** Open apertures provide unimpeded sound, but provide no protection from dust, liquids, or immersion. Designs with open apertures are highly susceptible to component failures and decreased device life, therefore this approach is not a feasible alternative. **Sealed housings** Sealed housings protect electronic devices by providing a barrier against water or dust, but prevent pressure and temperature equalization, as well as adequate sound transmission. As the device generates heat or experiences changes in pressure (due to going up in an elevator or an airplane, e.g.), pressure will build inside the housing. These internal pressure changes put significant stress on the housing seals which over time will fail, allowing water and contaminants to enter. This approach has similar downsides to non-porous covers, and therefore is not an alternative.

vi. Conclusion

For more than 20 years material suppliers like Gore and device producers have looked for alternative materials and methods for protecting communications devices, but nothing has proven capable of meeting sufficient performance as compared to the PFAS based vents. There has been significant incentive based on the high value and large number of users for this application.

[15] https://www.americanchemistry.com/industry-groups/center-for-the-polyurethanes-industry-cpi/resources/library/polyurethanes-and-thermal-degradation-guidance

c. Why a 13.5 year Transition Timeline is Required

The DSs have not specifically assessed the need for fluoropolymers and other PFAS in membranes for ingress protection, as the draft PFAS restriction is currently written, these products would fall under the default transition period of 18 months after EiF. We have demonstrated that no alternative is currently available which meets the performance requirements, and in the following we will illustrate the timeframe needed in the unpredictable case that a new material would be discovered or invented for this application.

Despite the high cost of raw materials[16] and the inherent incentive to find cheaper alternatives, no viable alternative materials have been identified and developed to date for use in communications devices. We, and other key actors in the supply chain, estimate it could take at least another five to ten years to identify and develop possible alternative polymer materials. This first step involves discovery, to which a specific timeline cannot be predicted.

Any possible alternative materials will then need further development to optimise them for specific application requirements (e.g., ingress protection and acoustic performance). We estimate that steps within this stage could take more than a year. The ingress protection and acoustic properties of these alternative materials will need to be evaluated to ensure that they provide adequate performance.

The final optimised material will then need to be manufactured into vent components so that reliability testing can be carried out, ultimately leading to creation of a new supply chain for assembly in devices that users may come to rely on.

Table 6. Estimated Timeline for Substitution

Steps for substitution	**What activities does this step entail?**	**Time required for step**
Discovery	Identify and develop suitable alternative materials. Material and process development from lab discovery to prototype scale. This will involve independent development of membrane and treatment technologies, as well as confirmation of their compatibility.	**Unknown** Estimate 5-10 years for this use
Development	Optimise material for specific application requirements (e.g. ingress protection and acoustic performance). This may involve transitioning processes to pilot scale or small-scale manufacturing.	1-2 years

[16] The Restriction Dossier refers multiple times to higher costs of fluoropolymers (Annex E, page 285, 390, 444, 458, 504, …)

Certification	Reliability testing of manufactured components, and initial validation of reliability in prototype device and/or representative testing.	1-2 years
Production	Investment, installation, and qualification of new mass production capability. Establishing robust material supply chain.	1-2 years
End Device	Development cycle of new communications device products, including establishing specific performance criteria (ingress protection, acoustic transmission, pressure equalization, etc.) in collaboration with end device manufacturer, developing tooling specific to individual devices, in-house and third-party testing, and validation of processes for conversion into parts for installation in devices.	1-2 year
Total		**9-18 years**

d. Material Use and Emissions

i. The amount of PFAS required for this end use is extremely low - less than 30 kg of PFAS are placed on the market in the EU each year

We estimate that the total annual number of new smartphones and wearable communication devices sold in the EU with IP67 or IP68 ingress protection ratings is approximately 129,000,000.

A typical vent for air and/or sound transmission for a smartphone has an estimated diameter of 4 mm (with an inner diameter of 1.6mm) and the thickness of the fluoropolymer membrane is about 0.007 mm. The typical density of the membrane in smartphone vents is about 0.4 g / cm^3 and a typical smartphone generally has four microphones (two at the bottom of the phone, one at the top of the phone and one on the back of the phone to assist with video recording) and two speakers (one at the bottom of the phone and one at the top of the phone). Therefore, the total amount of PFAS in a typical smartphone due to vents is estimated at about 0.2 mg which results in an estimated total annual weight placed on the market in the EU of about 30 kg per year.

ii. Ingress protection vents are not a significant source of emissions across their lifecycle

In September 2022, Gore provided a Socio-Economic Assessment (SEA) prepared by eftec and it has been shared with all five Dossier Submitters. Since this information was provided after the end of the Call for Evidence in September 2021, Annex I contains information from the SEA relevant to this derogation request.

Annex I describes the lack of the emissions associated with venting applications across different stages in the lifecycle.

Additional information on responsible manufacturing, processing and disposal of fluoropolymers and products made from fluoropolymers are provided in Gore's derogation request for fluoropolymers.

e. Socio-economic impacts

Vents in devices used for communications provide important functionality for their end users and wider society. EU consumers have come to rely on communication devices that provide high-quality acoustics and that can withstand exposure to water, oils and dust which are commonly found in environments where the devices are used.

Without a derogation, devices which both the general population and a wide range of professionals (police, emergency medical and fire services, military, transport operators, etc.) rely on for their daily and urgent communications would have an increased failure rate. This will lead to disruption to routine and critical communications and have a significant environmental and financial impacts on EU citizens.

- **Productivity and Safety Impact –** PFAS based vents are critical to the performance and reliability of communications devices which are essential to daily life and work for hundreds of millions of EU citizens. In addition to being important for daily communication and coordination, these devices are also used for critical communication with emergency services (medical, police and fire) and more recently have begun to track and report critical health care data including glucose levels, heart health data, along with automatic car crash and fall detection. A failed device is not just an inconvenience, it can delay or prevent critical lifesaving services.

- **Environmental Impact** – Management of electronic waste is an important priority. PFAS based mobile device vents prevent device damage and increase product longevity which in turn keeps millions of devices from being disposed each year. When a device prematurely fails, more waste is generated and critical raw materials, energy, and associated greenhouse gas emissions are required to replace these devices creating a greater burden on the environment.

In 2016, internal studies and industry reports[17] estimated that from 11% to as much as 30% of active mobile phones were damaged each year before high levels of Immersion Protection ratings were widespread. In 2022, there were approximately 250 million active smartphones in the EU with immersion protection. Assuming immersion protection vents are restricted, 11% of the 250 million smartphones in service at that future time which would have had immersion protection will become damaged and need to be replaced each year. That would generate an additional 5 million kg of electronic waste[18] to manage and 1.9 million tonnes of CO2 emissions[19] from replacements annually.

- **Financial Impact** – Without PFAS based vents, the rate of failed devices will increase significantly, creating a significant productivity and financial burden for EU citizens who must invest each year in replacement devices. Consumers could face a cost increase of greater than €600 per device due to replacement of prematurely failed devices, which at an EU level amounts to more than €16 billion per year.

  There would be an impact to industry as well. Communications devices represent a large and growing industry that generates significant income and supports a large number of jobs in the EU. Value chain disruptions from restricting a key component for communications devices may therefore significantly impact the EU economy.

f. Proportionality assessment

Annex I demonstrates that emissions from venting as a broad category of products are low, whilst the associated costs are very high. The adverse impacts induced by a potential restriction includes significant economic impacts throughout the value chain, impacts on employment (lost jobs) as well as adverse impacts on human health and the environment. **The costs of reducing PFAS emission through restricting venting products as a broad category is conservatively estimated at €130,000 – €1.2 million per kg PFAS emissions reduced. When specifically considering the restriction the much narrower use of ingress protection vents in devices which may be used for communications, higher costs per kg of PFAS emissions reduced can be expected.** This is indicated by the extremely low volume of PFAS required for this end use (~30 kg per year) and the more direct connection between the restriction of ingress protection vents and the increase in the consumption of critical raw materials and electronic waste due to replace destroyed smartphones and other communication devices, estimated at 27,500,000 devices per year.

[17] https://blog-idceurope.com/a-problem-with-mobile-phones-that-is-no-longer-acceptable-part-i/
[18] An average smartphone weights about 0.18 kg
[19] Conservatively estimated at 70 kg CO2 per device according to: https://www2.deloitte.com/us/en/insights/industry/technology/technology-media-and-telecom-predictions/2022/environmental-impact-smartphones.html

A cost effectiveness estimate does not, in itself, indicate whether benefits of a restriction outweigh the costs. For cases where risks and impacts of reducing exposure to a substance are unknown, it is common to compare the cost-effectiveness estimates with some type of benchmark. A study by Oosterhuis et al. published in 2017 found that for PBTs, vPvBs and substances with similar properties (e.g., lead) emission reduction measures with a cost-effectiveness below €1,100[20] per kg emission reduced were generally not rejected due to costs i.e., the costs were found to be proportionate. Measures with costs above €56,400[21] per kg, on the other hand, were more likely to be rejected, i.e., costs at this level were found to be disproportionate. Cost in between could be either proportionate or disproportionate – a so called 'grey zone' (Oosterhuis et al., 2017). The Oosterhuis benchmarks (BMs) have been used for the assessment of a number of regulations of PBTs and vPvBs, which are substances of very high concern (SVHCs). These BMs are, however, not necessarily applicable to substances of low concern such as PTFE and other PLCs. The reasoning behind this is that the implied willingness to pay (acceptability of costs) would be higher, the higher the perceived risk of a specific substance. If the Oosterhuis BMs are to be used for substances of low concerns, it is reasonable to make some indicative, quantitative or qualitative, adjustments. For example, if the 'grey zone' for a PBT ranges from €1,100 – €56,400 per kg PBT emission reduced, it is reasonable to assume that upper bound (and likely also the lower bound) would be significantly lower for substances of low concern.

There are uncertainties associated with all parts of the analysis and a multitude of impacts could not all be quantified and/or monetised. However, due to the consistent conservative approach taken it is believed that the most significant non-quantified impacts are costs of a possible REACH restriction and would therefore further strengthen the conclusions from the quantitative analysis. **It is therefore concluded that restricting the use of PFAS in products covered within this SEA will result in highly disproportionate societal costs for EU.**

[20] €1,000 in original study, uplifted to 2022 prices
[21] €50,000 in original study, uplifted to 2022 prices

[redacted]