SHPP's Inputs to the Public Consultation Comments to Annex XV PFAS Restriction Proposal

Question number 6: Missing uses: PTFE Used in Internally Lubricated Thermoplastic Compounds for Drinking Water and Water Management Applications

Executive Summary

SABIC's Specialties business (SHPP) produces a range of highly differentiated products, including high-performance thermoplastics, compounds, and additives that meet complex thermal, mechanical, optical, and electrical property requirements.

PTFE internally lubricated engineering thermoplastic (ETP) compounds are widely utilized in plastic compounds for drinking water and water management applications. Some examples are water meter impellers, water meter housings, faucet components, water purification components and more. These compounds offer differentiated properties, such as low friction and high wear resistance, resulting in self-healing and improved tribological properties. They extend the life span of devices or components, reducing plastic waste. In general, these compounds are more expensive than non-internally lubricated compounds and are only used when other materials fail to meet application requirements.

Tetrafluoroethylene is listed as authorized substance, entry FCM281, of Table 1 of Annex I to Commission Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food, subsequently, with water intended for human consumption.

A recent review published by the Society of Environmental Toxicology and Chemistry (SETAC) in 2023 states that emissions of PTFE during the use phase of final products are negligible because PTFE is bound within the PC resins and blends. The emissions in the waste stage depend on the pre-treatment method. PTFE does not release substances of toxicological or environmental concern, and fluoropolymers are stable and not expected to transform to dispersive nonpolymeric PFAS.

Evaluating the possible alternatives shows that no known alternatives provide the same performance functions and the same/better safety and socio-environmental benefits. Finding an alternative to PTFE in internally lubricated ETP compounds is challenging and would require at least 5-7 years of research and invention. Additionally, numerous tiers, OEMs and moulders across the globe would need to re-design and re-test their tooling, components and systems, which could take 7-10 years for water management customers to fully replace. Therefore, it could take at least 12-17 years to develop a new material solution with the same performance and environmental benefits as PTFE, and to replace it in existing applications.

Therefore, SHPP requests a 12-year derogation for PTFE used in internally lubricated engineering thermoplastic (ETP) compounds for drinking water and water management applications.

Substance Information:

Substance Name: Poly(1,1,2,2-tetrafluoroethylene)
Synonyms/Abbreviations: PTFE
Molecular formula: $(C_2F_4)_n$
EC/List no.: 618-337-2
CAS number: 9002-84-0
Type: Solid
Application: PTFE used in internally lubricated engineering thermoplastic (ETP) compounds for drinking water and water management applications

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1. Technical description

1.1 Application description

SABIC's Specialties business (SHPP) produces a range of highly differentiated products, including high-performance thermoplastics, compounds, and additives that meet complex thermal, mechanical, optical, and electrical property requirements.

PTFE internally lubricated engineering thermoplastic (ETP) compounds are designed to be converted by injection moulding and extrusion for use in components for drinking water and water management applications. These compounds typically comprise a base thermoplastic polymer and a fully or partially fluorinated polymer, such as PTFE, which serves the purpose of providing lubrication in the final moulded part. Additionally, these polymer formulations may include other additives and pigments, such as glass fibre reinforcements and/or mineral fillers.

ETP compounds containing PTFE are semi-finished products (plastic pellet) that are subsequently injection moulded or extruded into shapes or final parts. The main purpose of these ETP compounds containing PTFE is to reduce wear and friction between moving components and objects to ensure safe, reliable, and cost-effective functioning of the final product over its lifetime. As they are typically more expensive than compounds containing other lubricants or non-internally lubricated compounds, they are only applied by fabricators of parts when solutions or parts made from other materials fail to meet the application requirements.

These compounds are in many cases optimized for the specific requirements of the final applications. Some examples are:

- Building & construction, water management and drinking water regulatory approvals
- Wear and friction properties
- Mechanical properties
- Weight
- Noise reduction
- Vibration
- Chemical resistance
- Temperature resistance
- Cost

PTFE internally lubricated ETP compounds have been produced and sold over the last 40+ years. The differentiated properties of these materials have led to them being used in many different markets and have many different applications. In 2020, SHPP B.V. (hereafter "SHPP") sold around 18 different materials to close to 30 customers in the drinking water and water management market segment. As each customer typically makes many different devices and components with each material, the actual number of different parts impacted will be a multiple of this.

In many cases, the PTFE-containing compounds and the application-specific parts, like structural and safety critical components, must go through complex extended life testing to ensure the devices or components safely function over the expected or mandatory lifetime of the applications.

The moulds used to fabricate drinking water and water management components using the PTFE-containing compounds are often complex and designed to fabricate parts to very tight tolerances and to fulfil the applications' technical and regulatory requirements. Any significant change in composition/formulation of the compound, such as eliminating the PTFE and/or replacing it with a possible alternative, could result in needing to modify or replace the moulds to produce parts with the same final design and geometry. Also, a change in formulation or properties of the compound will likely trigger further mandatory design changes in adjacent parts that are not directly affected by this material change, because the parts must function together as a system in an assembly. Any of these changes could take years in drinking water and water management applications, depending on the complexity, materials used in fabrication and the number of tools per application.

Furthermore, the final assembly often needs to be completely re-tested and re-specified to ensure proper functioning over its lifetime. Drinking water and water management applications require extensive and sometimes severe long-term testing, which often requires several years of testing and validation to complete a substitution. Given the re-testing and re-specifying coupled with changes in design and production, part substitution can easily take several years to complete. If the application is regulated, safety critical, or both, it may take even longer.

Injection mouldable, PTFE internally lubricated ETP compounds designed for use in drinking water and water management applications typically consist of a neat base polymer, PTFE, and in some cases also glass reinforcements and/or mineral fillers. Some examples are water meter impellers, water meter housings, faucet components, water purification components, and more.

These PTFE internally lubricated compounds provide inherent wear and friction performance that eliminates the need for external lubrication (grease, etc.). This performance allows for increased application lifetimes and warranties (up to 40 years), the elimination of the need for servicing (re-applying regular lubrication, etc.), and reliable functioning of safety critical components. Some examples of current commercial applications of PTFE internally lubricated ETP compounds are described below.

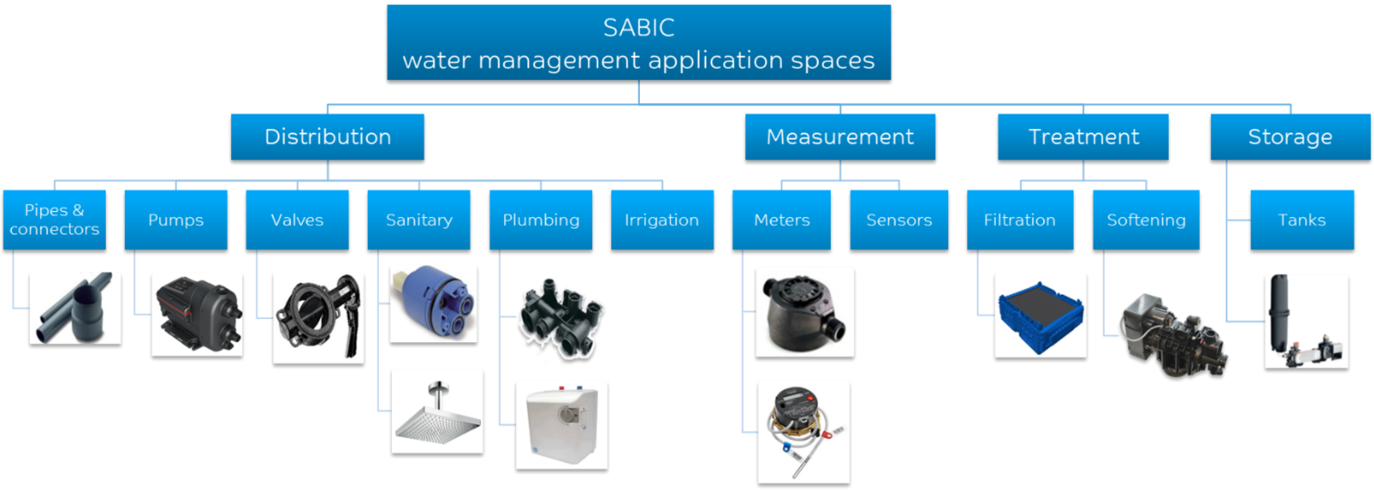

Figure 1 Water management application examples where lubricated plastics are used

Water meter impellers use PTFE self-lubricated engineering thermoplastic (ETP) compounds because of its long-term reliable wear and friction properties that ensure accurate measurement of the flow of water. This is particularly important when used in applications where the water meter provides data used to invoice people and companies for the water that is used/consumed from the water company/government.

Other application examples for PTFE self-lubricated engineering thermoplastic (ETP) compounds are impellers for industrial and household pumps that are used for:

- pool & spa
- drainage & irrigation
- fish tanks & ponds
- caravan & RV/camper
- coffee machines
- faucets & shower heads

1.2 Function of material/article and PFAS content

Depending on the specific requirements for the application, the PTFE internally lubricated ETP compound provides a tailored combination of lubricating effects, mechanical properties, chemical resistance properties, heat resistance and, if needed, electrical properties and flammability performance. These properties facilitate maintenance-free, reliable, and proper functioning of safety-critical moving parts in drinking water and water management components over an application lifetime that can be up to 40 years.

PTFE is used to optimize the tribological (wear and friction) properties of the compounds and articles that are made of it. PTFE, when used in self-lubricated engineering thermoplastic (ETP) compounds, is typically used in the range of 5-20% by weight.

PTFEs in self-lubricated polymer compounds provide a combination of high wear performance and chemical resistance. PTFE can also act as a drip suppressant for improved flammability performance as compared to other non-fluorinated internal lubricants [1].

PTFE has been utilized as an internal lubricant in a wide range of thermoplastic resin chemistries since the 1960s [2], resulting in an extensive understanding of PTFE grades, properties, and performance that is unmatched by other alternative internal lubricant systems. Additionally, PTFE's interactions with other fillers, including carbon fibre, glass fibre, mineral fillers, and flame-retardant additives, are well-known. This knowledge is difficult to replace.

The even dispersion of the lubricant additive into the base resin is critical in ensuring optimal performance in a thermoplastic compound. Poor dispersion can lead to a significant decline in critical mechanical properties, such as impact strength, and delamination of the moulded part. Furthermore, PTFE's hydrophobic nature provides distinct surface interactions when combined with other additives. Basically, an alternative internal lubricant, such as those discussed in Section 3.2, cannot be directly substituted to replace a PTFE-containing formulation and expect equivalent performance.

1.3 PFAS properties required in material/article

The PFAS used in these types of formulations is a fully fluorinated polymer - Polytetrafluoroethylene (PTFE). PTFE possesses distinct tribological properties. Due to its melt temperature and rheological character, neat PTFE cannot be processed by injection moulding. Instead, it must be sintered (compression moulded) at high temperatures to form shaped stock pieces, which are then machined into final parts. These parts are generally used in environments that require high chemical resistance at temperature and pressure, such as in the chemical process industry. Although neat PTFE exhibits very low coefficients of friction, it also exhibits high rates of wear due to its soft surface hardness.

When used as an internal lubricant in a thermoplastic resin, PTFE forms a layer on the wear surfaces, reducing friction between the wear parts and leading to reduced heat build-up and wear. In high-wear applications where a PTFE lubricated resin moulded part is used against steel, the PTFE layer forms on the steel as well. The PTFE chemically bonds to the steel surface through a reaction with the metal oxides present on the steel surface. This wear counterface film is continuously renewed through the wear process [3][4].

Figure 2 below shows how significant the improvement in wear is for PTFE containing thermoplastics across a range of resin types. Wear factor (K) is one measurement of the amount of wear resulting from contact and relative motion to another surface. This data was generated using ASTM D3702. If the result of the test is no wear the K value would be 0, so the larger the K value, the greater the wear.

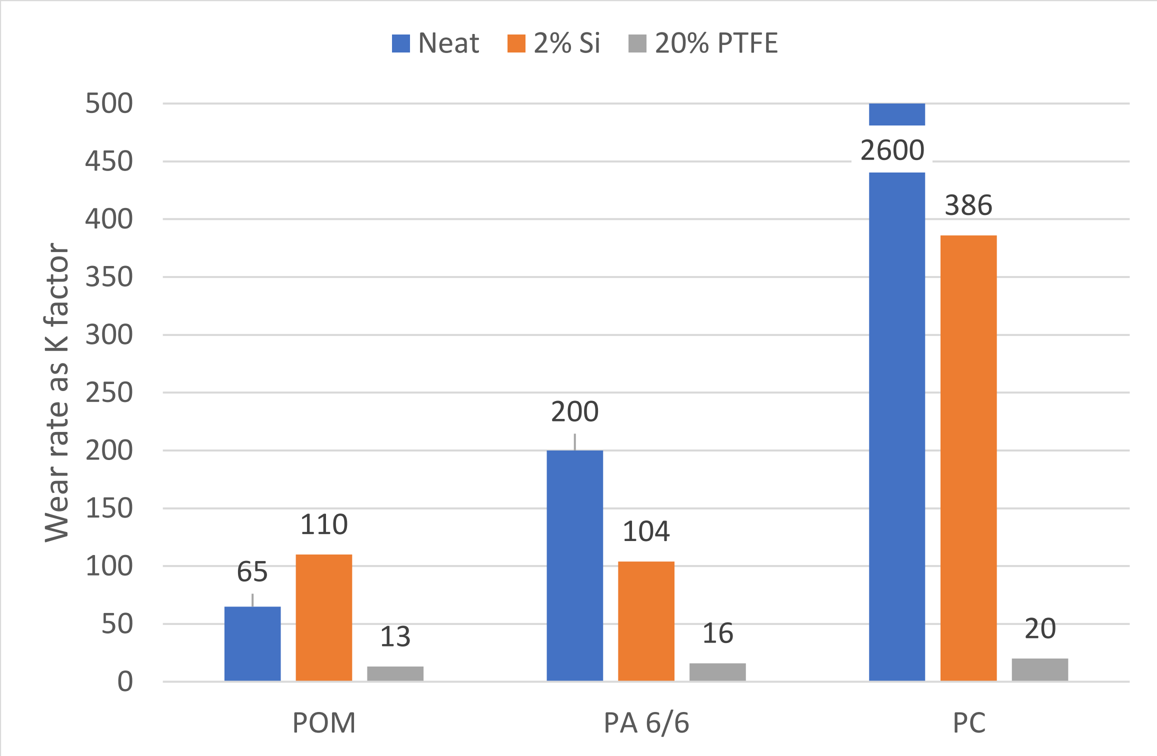

Figure 2 Change in wear of thermoplastic resin by adding PTFE or Silicone as internal lubricant.

For drinking water and water management applications, a non-exhaustive list of other properties that make PTFE a differentiated material as an internally lubricating additive in ETP compounds are its:

- food contact and drinking water regulatory properties
- high melting point
- high resistance to thermal degradation
- very high resistance to chemicals
- very low surface energy
- non-electrically conductive

PTFE is a class of polymer that encompasses a wide range of products, which mainly differ in molecular weight, molecular weight distribution, and final particle size of the powdered product. Over the last two decades, the process of producing these PTFE powders has been significantly modified to eliminate the use of PFOA and PFCA fluorinated surfactants as dispersants in aqueous phase emulsion polymerization. These surfactants were found to be environmentally persistent due to their relatively low molecular weight and high surface activity. PTFE suppliers have invested heavily in research to develop more environmentally benign surfactants [5], resulting in many REACH and POPs [6] compliant grades of PTFE.

The powdered form of PTFE is used as an internal lubricant in thermoplastic resin formulations. The powder is dispersed into the base resin, along with other formulation components, using a twin-screw extruder. The temperature, extruder/screw design, and extrusion conditions are optimized based on the specific formulation composition. The high shear environment of the twin-screw extruder is crucial to effectively disperse the PTFE and other additives into the base resin, resulting in a product mainly produced in pellet form.

This pelletized compounded material is subsequently used in injection moulding and/or extrusion processes with or without subsequent secondary operations such as machining of stock forms, assembly, bonding, etc.

The combination of the polymer and PTFE compounded together results in unique tribological properties versus the individual components: the compound immediately exhibits improved wear and friction properties and over time will display self-healing and further improved tribological properties. As a result, these types of PTFE internally lubricated ETP compounds significantly increase the lifespan of devices or components, thereby, reducing the number of new devices or parts needed and minimizing the amount of plastic waste generated during manufacturing and at the devices' end of life.

As PTFE wears, it leads to the formation of a strongly adherent and coherent transfer film. This film forms in the high shear/pressure/temperature environment at the wear interface between the internally lubricated part and the companion part in the wear pairing, which can be plastic or metal. The PTFE at this interface undergoes unique morphological and chemical changes to form films on both wear surfaces. When used against metals, the film can actually chemically bond into the metal oxide surface of the metal part. These films are continuously re-formed at the wear interface during use, making PTFE internally lubricated resins unique in many applications.

By reducing wear in these applications, PTFE lubricated resins reduce the energy required to power the assemblies in which they are used and increase the functional lifespan of these products. This, in turn, reduces replacement costs and the landfilling of these spent parts and assemblies. This trade-off needs to be considered when restricting the use of PTFEs. As an additive in a lubricated formulation, PTFE is generally used in loadings of 5-20 wt% of the bulk compounded product. Since the density of a perfluorinated polymer is higher than that of the base resin, the volume fraction of PTFE is lower than the weight percentage cited.

In contrast, externally applied lubricants, including those containing PTFE micro-powders, have a higher risk of ending up in the environment. This is because externally applied lubricants are often in a lower molecular weight grease base, which makes them more transitory. On the other hand, components or parts manufactured from internally PTFE lubricated plastic compounds can be and are recycled together with the rest of the assembly or application, which can prevent the PTFE from ending up in the environment.

In summary, PTFE internally lubricated Engineering Thermoplastic (ETP) compounds create a durable low-friction and low wearing layer on wear surfaces, improving the long-term reliability and performance of the contacting wear parts. The even distribution of PTFE within the resin ensures continuous re-forming of the high-performance film layer at the wear surfaces during use, effectively increasing the functional lifespan of all parts in the wear environment. The thermal and chemical resistance of PTFE also make it uniquely applicable for use in high temperature and chemically aggressive environments and applications when compounded into high temperature base resins such as PEEK and PPS [7][8]. These high-performance formulations are essential to industries requiring high temperature operations, high dielectric strength, and high chemical resistance.

Compared to the use of external lubricants, internally lubricated polymers are less likely to release fluorinated components into the environment, require less maintenance, and provide longer-lasting parts, ultimately reducing costs and waste.

1.4 European Drinking Water Regulations

In December 2020, the European Parliament formally adopted the revised **Drinking Water Directive**. The Directive entered into force on 12 January 2021, and Member States had two years to transpose it into national legislation. One of the objectives of the new Directive is to generate a set of European positive lists for starting substances, compositions or constituents of organic materials, which are authorised for use in the manufacture of materials or products in contact with water intended for human consumption. These positive lists shall take into account the existing positive list as a result of Article 5 of Regulation (EC) No 1935/2004 on materials and articles intended to come into contact with food (a.k.a. the "Union list of authorized substances" of Table 1 of Annex I to Commission Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food).

Tetrafluoroethylene is listed as authorized substance, entry FCM281, of Table 1 of Annex I to Commission Regulation (EU) No 10/2011, therefore continues to be allowed for use in organic materials intended to come into contact with drinking water.

2. End-of-Life

Emissions during the use phase of final articles are negligible, because PTFE is bound within the polymer. However, it is understood that anti-wear/anti-friction PTFE in products will eventually enter the waste stage with levels in the polymer matrix at 5-20% by weight.

In the waste phase some emissions could occur, the amount of which depends on the waste (pre-) treatment method, e.g., recycling/re-use, landfilling and incineration. Thorough incineration will decompose PTFE and prevent other PFAS from forming. When recycling/re-use and landfilling are chosen, PTFE remains a fluoropolymer that is not water soluble or mobile and therefore, does not present the specific hazards and risks of non-polymeric PFAS.

There is considerable data demonstrating that PTFE do not release substances of toxicological or environmental concerns [9].

2.1 Concerning exposure to the environment

A critical review on fluoropolymers was recently published (2023) in the Society of Environmental Toxicology and Chemistry journal Integrated Environmental Assessment. In this report, they state that emissions during the use phase of final articles are negligible, because PTFE is bound within the polymer. When these internally lubricated articles reach their end-of-life, various waste (pre-) treatment methods are commonly practiced by the industry, e.g., recycling/re-use, landfilling and incineration. Thorough incineration will decompose PTFE without formation of non-polymeric PFAS. When recycling/reuse and landfilling are chosen, polymeric PTFE remains as a fluoropolymer that is not water soluble or mobile and therefore, does not present the specific risks nor hazards as those of non-polymeric PFAS. There is considerable data demonstrating that PTFE do not release substances of toxicological or environmental concerns [9].

In contrast to non-polymeric PFAS, PTFE being a polymeric material is chemically, thermally, and biologically stable and therefore is not expected to transform to dispersive nonpolymeric PFAS when disposed of in landfill. A recent study presented results from OECD guideline biodegradation studies demonstrating that PTFE is stable under environmentally relevant conditions. Furthermore, fluoropolymers that meet the criteria to be considered Polymer of Low Concern (PLC), have negligible leachables, unreacted monomers, and oligomers most likely destroyed in fluoropolymer use processing and would therefore not be expected to significantly contribute to landfill leachate.

Available data reveal that fluoropolymers are mineralized (i.e., all C–F bonds broken, hydrofluoric acid generated, and scrubbed to calcium fluoride) under commercial Waste-to-Energy (WtE) incineration operating conditions. In recent pilot scale studies representative of full-scale WtE facilities, the most common form of end-of-life destruction conducted on PTFE found that combustion converted the fluorine into controllable hydrogen fluoride gas and that, of the 31 PFAS studied, no fluorine-containing products of incomplete combustion were produced above background levels. Further, a recent study investigating the presence of PFAS in waste incinerator flue gas stated: "based on a literature review, RIVM (the Dutch National Institute for Public Health and the Environment) expects that most of the PFASs will largely degrade during the incineration process and then be removed when the flue gases are cleaned. The remaining PFASs are expected to be removed during the recovery of the carbon dioxide". The RIVM report [10] affirmed that PTFE is the most stable fluorine-containing polymer. The RIVM report concluded that complete thermal decomposition of PTFE is achieved at a temperature of approximately 800 °C.

3. Availability of substitutes

3.1 Alternative applications

There are no known alternatives to PTFE used in internally lubricated plastics that result in the same differentiated tribological properties and application performance. Alternative formulations/compositions would require re-design and re-qualification of parts and would significantly risk not meeting the safety and performance requirements needed.

3.2 Alternative substances

Polymer compounds with silicone oil based lubricant vs PTFE lubricated polymers have:

- Potential safety risk due to malfunctioning and shorter application lifetime because the silicone oil will naturally self-migrate from the polymer as well as from the contact surface due to physical movement of the application and changes in viscosity due to temperature differences.

- Potential safety risk due to malfunctioning and shorter application lifetime because the silicone oil can damage other components in the application (i.e., electrical).
- Potential risk of manufacturing issues: painting and bonding operations can suffer from quality issues when silicone oil-based materials are used in the area.
- drinking water approvals not always possible
- Waste and cost issues due to the need to guarantee application performance by undergoing periodic inspections, maintenance and/or replacement of the entire device/system.

Polymer compounds with graphite based lubricant vs PTFE lubricated polymers have:
- Potential safety risk due to malfunctioning because the graphite generates a lot of fine debris when wearing.
- Potential safety risk due to malfunctioning and shorter application lifetime because the graphite only offers much less reduction in wear friction because of increased wear of the compound especially at higher temperatures.
  Waste and cost issues due to the need to guarantee application performance by applying periodic inspections, maintenance and/or replacement of the entire device/system.

Polymer compounds with olefin based lubricant vs PTFE lubricated polymers have:
- Potential safety risk due to malfunctioning and shorter application lifetime because the polyolefin offers much less reduction in wear friction.
- Waste and cost issues due to the need to guarantee application performance by undergoing periodic inspections, maintenance and/or replacement of the entire device/system.

Externally lubricated solutions (using greases, waxes, and oils) including those containing PTFE micro-powders vs inherently self-lubricating PTFE polymer blends have increased:
- Potential safety risk due to malfunctioning and shorter application lifetime caused by the loss of the external lubricant, which migrates away from the applied surface due to physical movement of the application and changes in viscosity due to temperature differences.
- Potential safety risk due to malfunctioning and shorter application lifetime because of debris, dirt and contaminants getting caught in the lubricant causing excessive wear and/or blocking.
- Potential for drinking water certification requirements not being met.
- Waste and cost issues due to the need to guarantee application performance by undergoing periodic inspections, maintenance and/or replacement of the entire device/system.

Table 1: Comparison of the tribological performance differences of various internal lubrication additives in PS base resin. Data generated using ASTM D3702 at 50 fpm, 40 psi, 23C and a steel counterface.

Internal lubricant	Wear Factor (K), lower value is better	Coefficient of friction (dynamic), lower value is better
10% PTFE	Baseline (51)	Baseline (0.33)
30% Graphite	>1500% Increase (799)	similar (0.30)
Silicone	No data, no commercial product available	
Olefin-based lubricant	No data, no commercial product available	

3.3 Health and environmental hazards of alternative to PTFE

Table 2: Comparison of health and environmental hazards of some alternatives to PTFE

Substance name	Cas no	EC no	Hazard Category	CLP Notes1	LogKow	BCF	PBT/vPvB	Uses	Additional information
Silicone oil/Polydimethylsiloxanes	63148-62-9	613-156-5	*Not classified*		8.21	3 397	No data found	Base oil (silicone)	May contain residual amounts of cyclic methyl siloxanes (D4, D5 and/or D6)
Graphite	7782-42-5	231-955-3	Not classified				Not applicable	Solid additive in lubricants	
olefin-based lubricant			Not classified					Solid additive in lubricants	

Source: Appendix E2 – Annex XV PFAS Restriction Proposal.

4. Development of possible substitutes

4.1 Actions taken to develop alternative applications or alternative substances

Externally lubricated materials (plastics and metals) and other internally lubricated plastic compounds could be used in some cases but at a considerable:

- Increase of cost
- Decrease of lifetime of the parts and devices
- Increase of waste
- Decrease of functionality to the end-user

Where the original PTFE internally lubricated ETP compounds were used for durability and safety reasons, replacement would also bring a significant increase in risk for the end-user caused by potential malfunctioning of the application.

4.2 Stages and timeframes needed to establish possible substitutes

First, currently there are no known alternatives to PTFE used in internally lubricated ETP compounds that result in the same distinct tribological properties and application performance (please refer to 3.2). An invention, therefore, will be necessary to develop a new solution without the negative consequences mentioned above for alternatives. It would take at least 5-7 years to develop such a material solution. Second, there are a vast number of globally located drinking water and water management tiers, OEMs and moulders that would need to re-design, re-test and re-certify their tooling, devices, assembly and systems made from PTFE internally lubricated ETP compounds to ensure the proper functioning of a new material solution and design. SHPP expects that our customers (actual parts/devices fabricators) would need at a minimum between 7 and 10 years to ensure all the PTFE internally lubricated ETP compounds are replaced in their drinking water and water management applications. In most cases, service/replacement parts for existing/in-use applications would need to be provided if the design cannot be modified, otherwise the entire application/device would need to be replaced. Overall, it is estimated that to develop a new material solution with the same performance, safety, and environmental benefits, as well as for the moulders and OEMs to re-design and re-test their tooling, parts, and devices, will take at least 12-17 years.

5. Request for derogation for use of PTFE used in internally lubricated thermoplastic compounds for drinking water and water management applications

Given the two derogation choices, SHPP respectfully requests a 12-year derogation. Since there are no PTFE alternatives available that can provide the same performance functions and the same/better safety and socio-environmental benefits, at least a 12-year derogation is absolutely needed. The material industry will need to develop a better solution (or equivalent) if possible, and all the moulders, tiers and OEMs from the drinking water and water management industry who use this type of material will need to re-design and re-test their parts, devices, and systems.

SHPP considers our derogation request as essentially different from the current derogation in the ECHA proposal for lubricants. Language in the proposal seems to indicate those PFAS-containing "lubricants" are traditional greases and oils (including those containing PTFE micro-powders in external lubricants) that are used in harsh industrial environments or for safety reasons.

Since the proposed derogation is only for PTFE, one additional point of reference is the UK's recently published PFAS regulation proposal. They limited their proposed restriction to certain and specific PFAS substances and did not apply the restrictions to an entire class of fluorine substances. Of particular note, they are excluding fluoroplastics and fluoroelastomers (such as PTFE, PVDF, etc.), which they consider as low hazard groups, from their proposed regulation. Presumably, this is because fluoropolymers (such as PTFE) are not water soluble, are not mobile, and do not present the same level of environmental hazards as low-molecular-weight non-polymeric PFAS. SHPP believes this also provides a basis for a total exemption of PTFE from the potential REACH restrictions if one is to be considered.

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