Summary

- Restriction proposal on PFAS misses all applications of usage sector **sanitary industry**
- Polymeric PFASs are used in many essential sanitary products
- Sanitary products are bound to normative requirements and country specific approvals and certifications

➔ **12-year derogation for the use of polymeric PFAS in the sanitary industry**

General Comments

Geberit International AG is the central management company of the globally operating Geberit Group, a European leader in the field of sanitary products. Geberit operates with a strong local presence in most European countries, providing unique added value when it comes to sanitary technology and bathroom ceramics. The production network encompasses 26 production facilities, of which 22 are located in Europe. Geberit employs over 11’000 people in Europe. The Group is headquartered in Rapperswil-Jona, Switzerland. In this respect, Geberit International AG as the central research and development unit of the Geberit Group is, among other things, responsible for (re-)developments and carries out official approvals of all kinds.

We welcome the opportunity to submit additional information during the public consultation phase on the restriction proposal on per- and polyfluoroalkyl substances (PFASs). We support the EU commission’s intension to restrict the use of PFAS and understand why action needs to be taken. Nevertheless, we believe that the restriction must take place within a time frame that leaves enough time for the switch to a PFASs-free alternative.

Until now, individual substances have been controlled and regulated by ECHA through REACH (Regulation (EC) No. 1907/2006). However, the proposed restriction on PFASs covers more than 10’000 chemical substances. With this broad definition of PFAS countless more sectors and sub-uses are affected by the restriction. The fact that there is no list with CAS numbers of the affected PFAS substances makes it even harder to identify all uses of PFAS in the whole supply chain. To identify PFAS not only in our internally produced products but also in the production process of our suppliers and sub-suppliers is very complex and time-consuming. This additional effort due to the huge number of substances involved should be taken into account in the timeline of the restriction process.

To avoid regrettable substitutions, the definition of PFAS should remain broad as presented. However, to ease the identifying process, we suggest that a list of today’s known PFAS chemicals with CAS-numbers is published.

In the restriction proposal the persistence of fluoropolymers is presented in a very one-sided and negative way. Persistence itself is not a hazard. The persistence of fluoropolymers does not necessarily have to be a negative characteristic. Fluoropolymer materials are often chosen because of their durability and resistance against degradation. They enable products with a long lifetime in harsh environments. Especially in the sanitary industry, these materials are key to build products with lifetimes of 50 years or even longer. According to the normative requirements from DIN EN 806-2 chapter 3.4.2 sanitary installations need to be designed for a service life of minimum 50 years. These sanitary products are installed in-wall and need to withstand harsh conditions in terms of pressure surges, temperature, and different water conditions (e.g., chlorinated).

The sanitary industry uses PFASs belonging to the category of polymeric PFAS. Fluoropolymers fit the definition of PFAS but show very different properties and are considered as polymers of low concerns (PLC) according to OECD.

The products of the sanitary industry are important to ensure the safe basic services of supply and distribution of drinking water and drainage of wastewater. Sanitary products are bound to normative performance requirements and in many cases require official approval. Additionally, the requirements for materials in contact with drinking water are neither harmonized globally nor within Europe. Nonetheless, it is mandatory to fulfil the national requirements to market the sanitary product in each country. In addition to the (re-)development effort, the renewal of the approvals requires an additional time frame of at least 3-5 years. For detailed information on approval processes, see confidential attachment A1.

Since the sanitary industry is an important pillar of modern society, this sector should be treated as an individual sector of usage within the restriction. So far, the restriction proposal misses the application of PFAS in the sanitary sector completely. We will provide detailed information on three exemplary use cases in Question 6 of the consultation form, but without claim to completeness.

Considering the following facts, that in the sanitary industry

- products are designed to have a long lifetime (minimum 50 years)
- products are bound to strict normative requirements and approvals
- only polymeric PFASs are used
- (re-)development, certification, and regulatory approval of PFAS free alternatives cannot be achieved within a five-year derogation period

we request a **12-year derogation** after entry into force (EIF) for application of polymeric PFAS in the sanitary industry.

Question 6: Examples for missing uses

Example 1: Water system pipes

Important products of the sanitary industry are piping systems. They are used as supply systems for drinking water, heating systems, or similar. Piping systems consist of pipes and matching fittings to connect the pipes. They are available in different dimensions. In this first example the focus is on the pipes and the second example will focus on the fittings. According to the KWD-globalpipe market study[1] one third of all sanitary pipe installations in Europe are done with multilayer pipes.

The multilayer pipes have a five-layer structure. They consist of two polyethylene layers with an aluminum layer in between connected via layers of a bonding agent. In the sanitary industry polyethylene, or more precisely raised temperature resistance polyethylene (PE-RT) is used to produce the pipes inner and outer layers. The PE-RT inliner is in direct contact with the drinking water and therefore this PE-RT type needs to fulfil high hygienic standards according to the drinking water regulations of different countries (e.g., Attestation de conformité sanitaire (ACS) for France or/ Bewertungsgrundlage für Kunststoffe und andere organische Materialien im Kontakt mit Trinkwasser (KTW-BWGL) for Germany). The pipes are not limited to a usage as drinking water supply system, but also used for heating systems. The PE-RT would be affected by the PFAS restriction proposal because it contains a PFAS additive.

In answer d)-g) we provide information on 6 different substitution ideas (Alternative 1.1-1.6) and discuss their feasibility. All alternatives have in common that the material must be changed or exchanged, which would require a new approval for drinking water applications and heating installation. The (re-)development, implementation, certification, and regulatory approval of all alternatives cannot realistically be achieved within a five-year derogation period. Detailed information on timelines can be found in confidential attachment A1. Therefore, the 12-year derogation must be applied for the sanitary industry.

a) *Annual tonnages and emissions and type of PFAS*:
   As a downstream producer of products containing fluoropolymers, we cannot estimate the annual tonnages at sub-sector level. However, we can provide numbers of our individual use. The annual amount of PE-RT and its PFAS content can be found in the confidential attachment A2. The type of PFAS used in the PE-RT is a polymeric PFAS.

[1] https://www.globalpipe.de/marketreports/

b) *Key functionalities provided by PFAS*:

The polymeric PFAS is added to the PE-RT as an additive. The polymeric PFAS additive enables continuous extrusion of the pipes with constant stable thickness and a smooth, defect free surface. The pipes must meet the highest requirements in terms of internal pressure resistance and durability. Even the smallest unevenness can hinder the functionality of the pipes. Precise extrusion is therefore essential for high-quality and fully functional piping systems.

c) *Number of companies estimated to be affected*:

We have no data on this topic.

d) *Availability, technical and economic feasibility, hazards and risks of alternatives*:

<u>Alternative 1.1: Metal piping system</u>

Technical: A technically feasible, already existing, alternative to the PE-Multilayer pipes are metal pipes. These piping systems can be made from different metals like steel, copper, stainless steel, or others.

Economic: From an economic point of view, the material costs of a metal pipe installation are about 100% higher than the cost of the same installation done with the PE-Multilayer pipes. For the exact calculations see confidential attachment A3. With this doubling of the cost, the economic feasibility of the metal piping system is not given for all applications.

e) *Alternatives not yet available – status of R&D*:

<u>Alternative 1.2: Replacement of PFAS additive in PE-RT with non-PFAS additive</u>

Our supplier of PE-RT material has informed us that the PFAS additive might be substituted. Currently they are testing different options. So far, the performance of the alternative additives does not reach the level of the PFAS additive, and this has negative effects on the surface properties of the extruded PE-pipe. More R&D work needs to be done to find an equivalent alternative. This development of a new PE-RT compound will take up to 3 years according to our supplier.

As soon as a suitable alternative additive is found, the production process of the multilayer pipes needs to be adapted to the new material properties. Since already a change in additives counts as a completely new material, the drinking water approvals as well as the mechanical approvals must be renewed. Therefore, at least 3 to 5 more years for the approval process need to be added to the development timeline before the new pipes can be put on the European market. For detailed information on the approval process and the cost involved, see confidential attachment A1.

f) *Substitution is technically and economically feasible, but more time is required*:

<u>Alternative 1.3: Usage of a different PE-RT</u>

Another alternative could be using a different PE-RT from a different supplier. Since we do not have any insights into the compound recipes, it is still unclear if this really would be an alternative or if different PE-RT grades potentially also contain PFAS additives. To qualify a new PE-RT material further testing and approval/certification time is required. The time to implement a new pipe material is around 3 years. The qualification phase includes mechanical tests and aging tests of the PE-RT material. These tests are long-term tests like the internal pressure creep test which already requires up to 10'000h (= 1 year + 51 days) according to ISO 9080. This is the only way to ensure the multilayer pipes will endure 50 years installed in-wall. After these initial qualifications, test specimens of the multilayer pipe need to be produced in all 16 dimensions (eight dimensions per system). These test specimens produced under serial conditions are later needed for the accredited tests at official test institutes to achieve certification. The pressure creep tests of 8760h (= 1 year) according to DIN EN ISO 21003 must be performed by an accredited test laboratory. This whole drinking water approval and certification will take an additional 3-5 years. See confidential attachment A1 for detailed information. Hence, a substitution will not be feasible within 5 years and therefore the 12-year derogation is required for this use.

<u>Alternative 1.4: Using different PE-Type – PEX instead of PE-RT</u>

Today, drinking water systems with multilayer pipes made of PEX instead of PE-RT are also on the market. PEX is a polyethylene with cross-linked bonds. There are different preparation methods for PEX: via peroxide crosslinking, silane crosslinking or electron beam crosslinking. PE-RT is more resource-efficient because no heat or irradiation process is needed for cross-linking. It is unclear if PEX is a PFAS free alternative, since the pipe extrusion remains identical, meaning there is the possibility that the same PFAS extrusion additive is used. As a downstream user we do not have insight into the detailed formulation of the PE compound. A change to PEX would also mean a complete material change as already described in alternative 1.3 mentioned above. However, switching to PEX would require even more time and effort than alternative 1.3 since an additional processing step (cross-linking) needs to be implemented at production site and additional investments in production machinery for the crosslinking are necessary. A timeframe of 5 years would not be sufficient; therefore the 12-year derogation is required for this use.

Alternative 1.5: Using PB pipe instead of multilayer-pipe

A technical, already existing, alternative would be to use single layer pipes made from polybutylene (PB). However, these PB pipes differ from the multilayer pipes in several ways. Since the PB pipes are monolayer pipes, they cannot withstand the same pressure levels as multilayer pipes at the same wall thickness. Also, to achieve the same diffusion-tightness as the multilayer pipes according to ISO 17455, necessary for heating installations or compressed air and vacuum applications, a higher wall thickness is needed. The higher wall thickness of the PB pipes would also affect the design of the corresponding fitting system. The thicker PB pipes cannot be connected with a press or plug-in fitting system. The fitting system must be based on welding (e.g., electrofusion) or the pipes must be joined via mirror welding. Also, today it is unclear if PB is available as an alternative, since we do not have insight into the confidential compound recipe and cannot ensure that no PFAS additive is used.

A change from the multilayer piping system to a PB piping system would require (re-)development of the pipes and the matching fittings and additional time for approval and certification. Similar to alternative 1.4. a timeframe of 5 years would not be sufficient, and the 12-year derogation is required.

g) *Substitution is not technically or economically feasible*:

Alternative 1.6: Using a different material class (glass, ceramics, wood) as pipe material

In the above-described alternatives, the material of choice is either metal or plastic. Other materials such as glass, ceramics or wood are not suitable for piping. Wood is problematic with regards to hygienic requirements and microbiological growth. Wood cannot pass the tests to be considered as a drinking water contact material. In addition, wood is also not suitable as an oxygen barrier with its oxygen permeability according to ISO 17455 being too high. For glass and ceramic materials, their brittleness is not compatible with the requirements for a piping system in terms of alternating loads described in DVGW W 534 Clause 12.9. Additionally, wood and ceramic pipes are not bendable/adjustable on construction sites and therefore not suitable for most installation situations.

Example 2: Fittings

Fitting systems are essential to connect the pipes and must be compatible with the drinking water pipes as described in Example 1. These fittings are available in all kinds of geometries and dimensions (e.g.: T-pieces, bends, reductions). One of the materials used for the fittings is the fluoropolymer PVDF. In answer d-g) we give information on 5 substitution options (alternative 2.1-2.5) and discuss their feasibility. We show that for all these PFAS-free substitution options a derogation period of 5 years is not sufficient to achieve certification and regulatory approval, therefore, we require a 12-year derogation for the sanitary industry.

a) *Annual tonnages and emissions and type of PFAS*:
As a producer of the products, we cannot estimate the annual tonnages at sub-sector level. However, we can provide numbers of our individual use in the confidential attachment A4. PVDF is considered a polymeric PFAS. From our suppliers we have confirmation that for production of the PVDF no other PFASs are used. The PVDF type used belongs to the category produced with NFS (non-fluoro-surfactants). Our products are expected to have no emission during product use (lifetime over 50 years). To check the PFAS emission from the fitting material into the water, a migration test and water analysis has been executed by an external laboratory. No PFASs were detected. The test report of the analytical laboratory can be found in confidential attachment A5.

b) *Key functionalities provided by PFAS:*
PVDF is the main fitting material. PVDF characterizes itself by excellent mechanical and resistance properties. Furthermore, the good UV resistance of PVDF material enables outdoor application, for example piping systems in greenhouses.

c) *Number of companies estimated to be affected:*
We have no data on this topic.

d) Availability, technical and economic feasibility, hazards and risks of alternatives:
<u>Alternative 2.1: Different existing piping system with PPSU fittings</u>
Technical: A technical, already existing alternative is the use of a different piping system with fittings made from PPSU.
Availability: Availability of PPSU after entry into force of PFAS regulation is unclear, since as a downstream user we cannot assure that PPSU production is completely PFAS free.

Risks: The application of multilayer pipes with PVDF fittings is not limited to drinking water. Due to the good resistance of PVDF against chemicals, they are widely used in industries, where piping systems are needed for all kinds of solvents and other chemicals. External influences such as cleaning agents or UV radiation are also no problem with PVDF. Since PPSU does not feature the same resistance, not all of the above-mentioned applications will be possible.

<u>Alternative 2.2: Using metal fittings</u>

Technical: Another technical alternative would be to use metal fittings with multilayer pipes.
Economical: From an economic perspective the metal fittings are more expensive than the ones made from PVDF. For example, the manufacturing costs of brass fittings are around 100% more expensive than PVDF fittings (see confidential attachment A6). For higher value alloys (e.g., stainless steel) the costs are even higher.
Risk: Metal fittings can corrode in certain environmental conditions. Therefore, it is essential to choose the right alloy for the local water quality. Important parameters of the water quality are the anion and cation content, pH value, and conductivity. The risk is to have cases of damage due to lack of corrosion resistance is much higher with the metal fittings than with the PVDF fittings.

e) *Alternatives not yet available – status of R&D:*

<u>Alternative 2.3: Alternative polymer (other than PPSU/PVDF)</u>

Another polymer fitting material besides PPSU and PVDF is not readily available yet. Research must be done by the polymer manufacturers. Finding a new polymer is not easy because the requirements are very demanding. Long term testing and aging tests need to prove that the material will be able to ensure a minimum product life of 50 years. The material must be resistant at elevated temperature for hot water systems. Hot water conditions are defined as follows:
Drinking Water application: 70°C during service life, Incident 95°C for 100h (EN 806-2)
Heating Systems: 80°C during service life, Incident 100°C for 100h (ISO 10508:2006)
Furthermore, a good chemical resistance against humidity and different water qualities (chlorine, sulphates, antifreeze, etc.) is mandatory. At the same time the material must fulfil high hygienic standards to be allowed in contact with drinking water. Such a development of a new material is not feasible within 5 years. And implementation to production as well as approval and certification of our product would need additional 5 years.

f) *Substitution is technically and economically feasible, but more time is required*:

Alternative 2.4: Substitution of PVDF with PPSU in our system

With PPSU, a reasonable alternative fitting material exists. The PVDF system could be produced from PPSU. The material change from PVDF to PPSU requires changes in the production process. PVDF is a semi crystalline thermoplastic, whereas PPSU is an amorphous polymer. This is why these materials are processed at different temperatures and show different shrinkage properties. Therefore, completely new injection molding tools are needed for all fitting geometries. This is associated with great effort in terms of engineering. Completed development, procurement of all tools necessary, and production process will take at least 4 years. Investment cost can be found in confidential attachment A7.

As already mentioned above in Alternative 2.1. PPSU is not as resistant as PVDF. Therefore, there is a risk that the expected service lifetime of PPSU fittings is adversely affected due to external influences (e.g., UV radiation).

g) Substitution is not technically or economically feasible:

Alternative 2.5: use a different material class (glass, ceramics, wood)

Materials such as wood, glass and ceramics are not feasible for the same reasons mentioned in Example 1, Alternative 1.6 above.

Example 3: PTFE coatings on sealings

It is impossible to imagine the sanitary industry without sealing rings. For example, the connection between pipes and fittings are sealed with O-rings. The demands on the sealings are high because they have to be functional over the entire lifetime of these products of more than 50 years.

a) *Annual tonnages and emissions and type of PFAS*:
The coating is made with PTFE a PFAS of the fluoropolymeric type. No information on tonnages can be given since we buy the sealings already coated and do not process the PTFE ourselves. The total amount of PTFE is small, since the coating thickness is in the micrometer range.

b) *Key functionalities provided by PFAS:*
The PTFE coating provides outstanding anti-friction properties. PTFE is the material with one of the lowest known friction coefficients. This enables easy mounting of the sealing without causing any damage to the sealing. PTFE is a material without any hygienic hazards and can be used for drinking water applications. Furthermore, the PTFE coating protects the sealing against chemical attack. At production sites, the PTFE coating prevents the sealings from sticking together. Additionally, PTFE coatings can be colored and therefore allow the user an easy differentiation between different types of sealings.

c) *Number of companies estimated to be affected:*
We have no data on this topic.

d) Availability, technical and economic feasibility, hazards and risks of alternatives:
<u>Alternative 3.1: Talcum</u>
Technical: Instead of PTFE coatings the sealings could also be treated with talcum. Since it is not a coating, talcum is not covering the surface completely. Talcum is a powder and applied in a lose fashion. It prevents the sealings from sticking together and allows efficient automated mounting of the sealings in production. The properties of talcum and PTFE are different. Talcum never reaches the level of PTFE in terms of sliding friction. Moreover, talcum is not permanently fixed to the sealing surface and will not stay on the surface for the whole product lifetime. This makes talcum only suitable for static application of the sealing. Therefore, talcum is not a technically equivalent alternative for all applications where we are using PTFE coatings.

Risks: Since the sealings are never fully covered with talcum, talcum cannot protect the sealing surfaces from chemical substances. The friction coefficient is different for talcum and PTFE, so the functionality of the sealing will not be the same. These two factors can be a risk as we do not know their impact on long-term behavior for the lifetime of our product.

<u>Alternative 3.2: Lubricants</u>

Technical: Another method to ensure easy mounting of the sealings without the sealings getting stuck or twisted, is to use liquid lubricants. The lubricants will be washed out during the use phase in the water supply/drainage system and will not adhere to the sealing surface for the whole product lifetime, similarly to talcum described above. The availability of lubricants with drinking water approval is limited.

Silicone: Silicone is a lubricant compatible with many sealing materials like EPDM or NBR and allows easy mounting of the sealings. But usage of silicon is not LABS conform (paint wetting impairment substances, VDMA 24364) which would preclude use of installations with such sealings in the automotive industry, for example. There are different silicon lubricants with drinking water approval on the market. The problem is these silicone-based products also contain PTFE and are therefore not PFAS free. The data sheet of a commonly used product in sanitary industry is attached in confidential attachment A8.

Glycerin: Glycerin can also be used as a lubricant. The disadvantage of glycerin is that it dries out over time and can become sticky, or that it is completely washed out with the water and does not provide long-term lubrication.

Risks: Lubricants do not have the same functionality as a PTFE coating. They cannot protect the sealing from chemical substances, and they can be washed out over time. Therefore, no long-term functionality of lubricants is given, and this might have unknown influence on the lifetime of our products.

e) Alternatives not yet available – status of R&D:

<u>Alternative 3.3: New coating without PTFE</u>

One of our suppliers informed us that they are working on an alternative coating without PTFE. Since we are not directly involved in the development process, we cannot give information on the R&D status. Thus far, the alternative coating does not reach the level of PTFE in terms of sliding friction. After our supplier has a suitable coating for our applications, the supplier has to approve its product for the use in contact with drinking water. Afterwards we require at least another 3-5 years for further R&D work for implementation and upcoming approvals and certifications.

f) Substitution is technically and economically feasible, but more time is required: -

g) Substitution is not technically or economically feasible: -